

ADDRESSING THE CHALLENGE OF CHILDREN WITH FOOD ALLERGIES

HEARING

BEFORE THE
SUBCOMMITTEE ON CHILDREN AND FAMILIES
OF THE
COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS
UNITED STATES SENATE
ONE HUNDRED TENTH CONGRESS
SECOND SESSION
ON
EXAMINING THE CHALLENGE OF CHILDREN WITH FOOD ALLERGIES

MAY 14, 2008

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ADDRESSING THE CHALLENGE OF CHILDREN WITH FOOD ALLERGIES

WEDNESDAY, MAY 14, 2008

U.S. SENATE,
SUBCOMMITTEE ON CHILDREN AND FAMILIES,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:34 p.m. in Room SD-430, Dirksen Senate Office Building, Hon. Christopher Dodd, chairman of the subcommittee, presiding.

Present: Senators Dodd and Alexander.

OPENING STATEMENT OF SENATOR DODD

Senator DODD. I want to thank you all for being here. We'll take a couple of minutes and make some opening comments and turn to my good friend Senator Alexander for any opening comments he has. Then we'll get to Dr. Fauci and our panelists. I'm deeply honored you're all here today and I want to thank you for being part of this important hearing.

Today's hearing will focus on a growing and serious public health and safety challenge to our Nation's children, and that is food allergies. The number of Americans with food allergies has nearly doubled in the past 5 years, from 6 million to some say more than 12 million. Rates among children, especially young children, have doubled as well. Today more than 3 million children have food allergies for which there is no known cure, and that number is growing, as is the number of children who go into anaphylactic shock because of their allergic conditions.

It is particularly fitting to be holding this hearing today because this week is National Food Allergy Awareness Week. National Food Allergy Awareness Week offers us the opportunity to heighten food allergy and anaphylactic awareness and redouble our efforts to educate schools, child care centers, parents, restaurants, and the public at large about the dangers associated with them. It's our hope this afternoon that today's hearing will shed light on this growing national problem.

For me this is a very personal issue, one my wife Jackie and I face every single day. Our daughter Grace, who is 6½ years of age, has severe food allergies that have sent her into anaphylactic shock four times already. It's a terrifying moment, one that does not get easier. As parents, we had to come to grips with how to manage her condition. We had to educate not only ourselves, but everyone

in our daughter's life, from her school to her teachers, to her friends and their parents, to her babysitters.

As we will hear from our witnesses this afternoon, being the parent of a child with a food allergy means being in a constant state of awareness and vigilance. It means not only having a plan in place at home and at school for avoiding contact with your child's known allergy, it means being prepared to act immediately should they be accidentally exposed to an allergen.

The best known method of treatment for food allergies is strict avoidance of the foods to which children are allergic. Even with the best of intentions, each year approximately one out of four people with food allergies has an accidental exposure that leads to an allergic reaction. As we will hear later this afternoon, in the most tragic situations even the best laid plans and the most attentive, caring parenting may not be enough to save a child's life.

While any food can potentially cause an allergic reaction, eight foods account for about 90 percent of all food allergy reactions. They are peanuts, tree nuts, milk, eggs, fish, shellfish, soy, and wheat. Each of these foods is so common in our society that avoiding them completely is nearly impossible, especially in settings outside of the home. That makes readily available information particularly crucial.

Congress took a good step toward improving the ingredient labeling of foods, for allergens, when it passed the Food Allergen and Consumer Protection Act of 2004. I think we must do more, and I believe we can start with our schools, where our children spend most of their days. Schools, school administrators and teachers are critical partners for managing students' food allergies within their walls. In order to manage them effectively, I believe it will require guidance from the Federal Government on best practices the schools can then tailor to their individual needs. In addition, with many of our school districts lacking the funding necessary to implement a food allergy management plan, it will also take some resources.

Some States are already doing this and I commend them. Connecticut and Tennessee I would point out are two of the eight States that are actually taking steps in this area. Connecticut, I'm proud to say, was the first in the country to enact legislation requiring school-based guidelines concerning food allergies and the prevention of life-threatening incidents in schools.

This week I had the wonderful opportunity to visit Washington Elementary School in West Haven, CT, where I learned about the programs they have put in place to protect the 16 students in their school in K through 5 in the current student population who have food allergies. As they told me, dealing with this problem takes time, it takes resources, and it takes a willingness on the part of the school and the parents to put an effective plan in place.

Several other States have passed or are close to passing laws developing school-based guidelines concerning their food allergies; in addition to Tennessee and Connecticut, Massachusetts, Vermont, New Jersey, Arizona, Washington, and New York. Without Federal guidance and standards, a child's health and safety may be protected in one school but not in another. Policies may vary among schools within the same school district.

I've introduced legislation called the Food Allergy and Anaphylactic Management Act that will address the critical need for a uniform and consistent policy for schools with resources to help them act. It's all voluntary. It doesn't mandate anything, but gives schools ideas that work, so they don't have to do it all on their own and start *de novo*. It is my hope that we can move this legislation as soon as possible. What is at stake is nothing less than the health and safety of millions of our children.

We have two outstanding panels of witnesses today to help us gain a better understanding of why we've seen such a dramatic increase in the number of children with food allergies and what kind of research is currently taking place. We're going to hear from Dr. Tony Fauci, who is the distinguished Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. We'll also hear from Dr. Hugh Sampson, one of the country's preeminent experts in food allergies, from Mount Sinai Medical School in New York, and the President of the American Academy of Allergy, Asthma, and Immunology.

Many more leaders in the effort to raise public awareness and to advocate for families suffering from food allergies are in our audience today. I would especially take a moment to commend the work of the Food Allergy and Anaphylaxis Network, an organization with whom I have worked for many years. One of their advocates from Connecticut is here today, Mary Ericson, and her son Kyle, who I had the pleasure of meeting yesterday, who I'm also proud to say is a devout Red Sox fan, and I thank him for that as well. We like to know those things if we can—who actually looks like a Senator, I think, in that good outfit he's got on here today.

They have been in my office in the past years sharing Kyle's personal story with me and others in the Connecticut delegation, about what life is like being a 10-year-old with a severe allergy problem to peanuts and tree nuts, as Kyle has.

I ask unanimous consent to put the written testimony of Kyle's mom Mary in the record.

I'd also like to put a statement in the record from a lifelong food allergies sufferer, Jo Frost, who's probably better known through a role as television's Super-Nanny.

[The information referred to can be found in Additional Material.]

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

I want to welcome my colleagues and our distinguished witnesses for being here today. Today's hearing will focus on a growing and serious public health and safety challenge for our Nation's children, and that is food allergies. The number of Americans with food allergies has nearly doubled in the past 5 years, from 6 million to more than 12 million. Rates among children, especially young children, have doubled as well. Today more than 3 million children have food allergies for which there is no known cure—and that number is growing, as is the number of children who go into anaphylactic shock because of their allergic conditions.

It is particularly fitting to be holding this hearing today because this week is National Food Allergy Awareness Week. National Food

Allergy Awareness Week offers us the opportunity to heighten food allergy and anaphylaxis awareness and re-double our efforts to educate schools, child care centers, parents, restaurants, and the public about the dangers associated with them. It is my hope that today's hearing will shed light on this growing national problem.

For me, this is a very personal issue—one my wife Jackie and I face every single day. Our daughter Grace has a severe food allergy that has sent her into anaphylactic shock four times. She is only six years old. It is a terrifying moment—one that does not get easier. As parents, we had to come to grips with how to manage her condition. We had to educate not simply ourselves but everyone in our daughter's life—from her school and teachers, to her friends and their parents, to her babysitter.

As we will hear from our witnesses, being the parent of a child with a food allergy means being in a constant state of awareness and vigilance. It means not only having a plan in place at home and at school for avoiding contact with your child's known allergy, it means being prepared to act immediately should they be accidentally exposed to an allergen. The best known method of treatment for food allergies is strict avoidance of the foods to which children are allergic. But even with the best of intentions, each year approximately 1 out of every 4 people with food allergies has an accidental exposure that leads to an allergic reaction. And as we will hear today, in the most tragic situations, even the best laid plans and the most attentive, caring parenting may not be enough to save a child's life.

While any food can potentially cause an allergic reaction, 8 foods account for 90 percent of all food allergy reactions. They are peanuts, tree nuts, milk, eggs, fish, shellfish, soy and wheat. Each of these foods is so common in our society that avoiding them completely is nearly impossible, especially in settings outside the home. That makes readily-available information particularly crucial.

Congress took a good first step toward improving the ingredient labeling of foods for allergens when it passed the Food Allergen and Consumer Protection Act in 2004. But we must do more.

We can start with our schools where our children spend most of their days. Schools, school administrators and teachers are critical partners for managing students' food allergies within their walls. In order to manage them effectively, I believe it will require guidance from the Federal Government on best practices that schools can then tailor to their individual needs. In addition, with many of our school districts lacking the funding necessary to implement a food allergy management plan, it will also take resources.

Some States are already doing this. Connecticut and Tennessee, two of the States represented here, are among them. Connecticut, I am proud to say, was the first State in the country to enact school-based guidelines concerning food allergies and the prevention of life-threatening incidents in schools. This week, I had the opportunity to visit Washington Elementary School in West Haven, CT where I learned about the programs they have put in place to protect the 16 students in the current student body who have food allergies. As they told me, dealing with this problem takes time. It takes resources. And it takes willingness on the part of the school and the parents to put an effective plan in place.

Several other States have passed laws developing school-based guidelines concerning food allergies including Massachusetts, Vermont, New Jersey, Arizona, Washington and New York. But, without Federal guidance and standards, a child's health and safety may be protected in one school but not in another. Policies may vary even among schools within the same school district.

I've introduced legislation—the Food Allergy and Anaphylaxis Management Act—that will address the critical need for a uniform and consistent policy for schools with resources to help them act. It is my hope that we can move this legislation as soon as possible. What is at stake is nothing less than the health and safety of our children.

We have two outstanding panels of witnesses with us today. To help us gain a better understanding of why we've seen such a dramatic increase in the number of children with food allergies and what kind of research is currently taking place. We will hear from Dr. Tony Fauci, who is the distinguished Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. We will also hear from Dr. Hugh Sampson, one of this country's preeminent experts in food allergies from Mount Sinai Medical School in New York and the President of the American Academy of Allergy, Asthma, and Immunology.

Many more leaders in the effort to raise public awareness and to advocate for families suffering with food allergies are in the audience today. I would especially like to take a moment to commend the work of the Food Allergy and Anaphylaxis Network, an organization with whom I have worked for many years. *One of their advocates from Connecticut is here with us today. Mary Ericson and her son Kyle are in the audience.* They have been to my office in past years, sharing Kyle's personal story with me and others in the Connecticut delegation about what life is like being a 10-year-old with severe allergies to peanuts and tree nuts.

I ask unanimous consent to put the written testimony of Kyle's mom Mary in the record. I would also like to put a statement in the record from life-long food allergy sufferer Jo Frost, who is probably better known through her role as television's *Supernanny*.

Thank you.

Senator DODD. With that, I will turn to the Ranking Member of the Children and Families Subcommittee, my distinguished colleague from Tennessee, who I'm always proud to work with, Senator Alexander, for his opening statement.

STATEMENT OF SENATOR ALEXANDER

Senator ALEXANDER. Thank you, Senator Dodd.

Senator Dodd has been a preeminent advocate for children a long time before he had any. He's done very important work in the U.S. Senate. It's a privilege to work with him on this subcommittee. His personal interest in this subject because of his own children makes him even more effective. So, I salute him for the hearing.

We're here today to learn about what the Federal Government can do to help schools and places outside the home do a better job of dealing with and helping children and families of children who have food allergies.

Of course, the other thing we can do in the U.S. Senate is to help make Americans aware of this. Most of us are not aware of the seriousness of the food allergy problem or have just recently become aware of it.

I want to especially welcome to the hearing Ronda Adkins. She and her husband Trace in Tennessee have done a terrific job of helping make Tennessee more aware of this problem, and I'm sure had a major role in our State's movement to deal with food allergies. I'll have a chance in a few minutes to introduce Colene Birchfield, a music teacher from Ooltewah who is going to be one of our witnesses.

I'm interested in learning today especially how we can be effective. Sometimes we're ham-handed here in the Federal Government and we take an action and proclaim a result and it really doesn't help that much. Senator Dodd is being very sensitive here to think about how can we really make things happen in the 105,000 public schools with 55 million students? What can we do here that makes it easier for them to do a better job.

So I am anxious to learn. I thank the Senator for having the hearing. I thank the families for coming. I recognize this is a tremendously serious problem, about which I'm anxious to learn more and on which I expect to continue to work.

Senator DODD. Very good. Thank you. Thank you very much, Senator.

Dr. Fauci, we thank you immensely for being with us. I have a lengthy introduction of you to give this morning, but I'll just include it in the record. You've been before this panel I don't know how many times over the years and you're so highly regarded and respected. I know you hear that from others, but we're deeply honored you'd spend some time with us today and talk about this, an area you're not unfamiliar with at all given your background and experience.

We welcome you here once again, and thank you for your service to our country.

[The information referred to follows:]

INTRODUCTORY REMARKS FOR ANTHONY S. FAUCI, M.D.

- On our first panel, we will hear from Dr. Tony Fauci who is the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, a position he has held since 1984.

- As NIAID Director, Dr. Fauci oversees a budget of \$4.4 billion and an extensive research portfolio of basic and applied research to prevent, diagnose, and treat infectious diseases such as HIV/AIDS, tuberculosis, and malaria. The NIAID also supports research on transplantation and immune-related illnesses, asthma and allergies.

- His contributions in the field of immune-mediated diseases and infectious diseases are tremendous and he has been the recipient of some of this Nation's top honors in biomedical research and public service.

- He is a native of Brooklyn, NY and did his medical training at Cornell University and The New York Hospital.

- We thank you for being here today.

**STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR,
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS
DISEASES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD**

Dr. FAUCI. Thank you very much, Mr. Chairman and Senator Alexander. Thank you for those kind comments and thank you for giving me the opportunity to testify before this committee on the problem that you outline so well, one that is growing in seriousness and in scope.

I show this first visual here really, which is a quite dramatic representation of what some children and even adults have to go through. It's a picture, for those who can see it, of a young child with a gas mask on and a peanut butter sandwich in one hand and milk in another. Although it's an exaggerated schematic, what it really tells us is the dire straits that many children find themselves in; and also, being on the cover of Newsweek, the fact that this is something that is now getting growing awareness—which is part of the solution of the problem, getting increased awareness.

I'm going to tell the audience and you some things that you, because of your own personal experience, already know and that is the scope of food allergy in the United States, with 6 to 8 percent of children under age 4 have a food allergy and about 4 percent of adults; an estimated 30,000 anaphylactic episodes per year, which are serious physiological phenomenon that can actually lead to the death of an individual. In fact, approximately 150 to 200 deaths occur per year, an average of about 2 or 3 per week.

Peanut allergy, as you know, is the most common cause of fatal or near-fatal anaphylaxis and some food allergies, such as peanut allergy, actually persist throughout life. Other allergies, such as with eggs and milk, tend to dissipate as you age.

The treatment and prevention of food allergy. There are few treatment options and in fact these have not changed significantly over a very long period of time. That'll get to the point that I'll make about the need for research and getting new people in the field. The treatment is with antihistamines, which block some of the mediators that are responsible, as well as epinephrine. These are the same things that I used in medical school myself decades ago. We haven't really had any significant increase in our knowledge about the types of therapeutics that need to be used.

As you know, severe reactions require epinephrine and IV fluids. As you mentioned so correctly, allergen avoidance is the only prevention approach. The trouble with allergen avoidance is that, even innocently on both parts, there's the accidental exposure that is all too common, that can lead to not only discomfort and even death, but also the constant fear that there'll be a catastrophic event beyond the control of the individual.

The NIH has been funding food allergy for several years. I show on this slide some good news and some sobering news. If you look from 2003 to 2008, there has been a dramatic increase in resources from around \$2 million up to over \$13 million. The increase is the good news. The sobering news is that's still not nearly enough to do the kinds of things we need to do, particularly enticing bright new investigators into the field.

Speaking of research, there are three major components that I put before you. We can definitely go into these a bit more during

the questions. The first is the basic research on immunology and allergic mechanisms, in other words to understand the underlying mechanisms of why and how children and adults get these types of reactions.

The other is an epidemiological study, what is the scope and the circumstances under which these types of reactions occur. Then finally, doing research there is what we call pre-clinical research, namely either in a test tube or in an animal, and some clinical research. A couple examples are shown there and are in my written testimony which I've submitted for the record. For example, pilot trials of how you desensitize or tolerize a child or an adult to not react to exposures, and there are alternate methods of administration of allergens that'll do that. Also, to question the classic paradigm of whether avoidance early on in life or actually exposure to high dose early on in life might have the beneficial effect of tolerizing an individual.

I refer specifically to a program that is called Exploratory Investigations in Food Allergy. It's a 2008 initiative for about \$3.5 million. The objectives are two-fold and important. First and obviously is to study the scientific mechanistic studies of food allergies, but even more importantly it's to attract new investigators to the field. You mentioned we have Dr. Hugh Sampson in the audience, who is a superstar in food allergy. The number of his colleagues that he would need to push the field forward is really very, very small. We need to get a cadre of new, young investigators involved in the field, and I'm happy to say that the numbers of applications that are coming in in response to that request for applications is now, happily, disproportionately weighted toward new people who want to get into the field, who've not been in the field before.

Also, as you know, we've partnered, as you mentioned, with a number of organizations, including EPA and the Food Allergy and Anaphylaxis Network, the Food Allergy Project, et cetera.

I'd like to close on this last visual, which is something that we believe is going to have an important impact. We were approached by a number of constituency groups and professional societies to take the lead in developing guidelines for the diagnosis and the treatment of food allergy. Starting in July 2008, we will be coordinating the development of guidelines that could be used. We anticipate more than 20 professional societies, advocacy groups, and other institutes. Hopefully, this type of an approach will help not only the clinicians, but also their families and the families of the children who are so drastically and dreadfully addressed with these particular problems.

Again I want to commend you for calling this hearing because we really do need to call attention to it. That's a very important part of how we're going to solve this problem.

Thank you, Mr. Chairman. Thank you, Senator Alexander.

[The prepared statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D.

Mr. Chairman and members of the subcommittee, thank you for the opportunity to discuss with you today food allergy and the research being conducted and supported by the National Institutes of Health (NIH) to address this public health problem. Within NIH, the National Institute of Allergy and Infectious Diseases (NIAID) is the lead institute for research in this area, although other NIH Institutes and

Centers support basic research relevant to food allergy. I am particularly pleased to be here with you as we recognize the 11th Annual Food Allergy Awareness Week and commend your efforts to bring attention to this important issue.

OVERVIEW OF FOOD ALLERGY

Food allergy is much more than an inconvenience; the effects of food allergy can be devastating and sometimes deadly for those afflicted. During an allergic response to food, the immune system overreacts to certain components of foods, setting off a cascade of immunological events that leads to symptoms ranging from itchy hives to anaphylaxis. Anaphylaxis is a severe and life-threatening systemic allergic reaction characterized by fall of blood pressure, upper airway obstruction, and difficulty breathing. Food allergy causes an estimated 30,000 episodes of anaphylaxis each year, accounting for approximately one-third to one-half of all anaphylaxis-related emergency room visits. Food allergy also causes an estimated 100 to 200 deaths per year in the United States. It is truly sobering to consider that, as a consequence of food allergies, two or three otherwise healthy Americans—usually adolescents or young adults—may lose their lives this week. Even with diligent avoidance of known food allergens, it is estimated that each year, one of every four food-allergic individuals will have an accidental exposure that leads to a food-induced allergic reaction.

Food allergies affect approximately 6 to 8 percent of children under 4 years of age and about 4 percent of adults in the United States. Evidence suggests that the prevalence of food allergy is increasing, especially peanut allergies, which tend to persist throughout life. Severe, life-threatening reactions occur mostly in adolescents and young adults, and peanuts and tree nuts are the most common causes of such reactions. Currently, the only proven interventions for food allergy are allergen avoidance and treatment with antihistamines, and intravenous fluids and epinephrine for more severe reactions.

Food allergy affects the health, nutrition, development, and quality of life of children and adults. Because a history of mild reactions does not preclude the occurrence of future life-threatening reactions, food allergies can also have disconcerting psychological effects related to fears of serious reactions and the stigma related to avoidance of common foods and social gatherings. As you are undoubtedly aware, this is a particular problem for children in school lunchrooms and other social settings where others may minimize or fail to understand the seriousness of the allergy. The increasing prevalence of certain food allergies, their persistence throughout life, the potential for fatal allergic reactions, and the lack of preventive approaches other than food avoidance have all contributed to the emergence of food allergy as an important public health problem.

CURRENT NIAID RESEARCH ON FOOD ALLERGY

NIAID is the principal sponsor of food allergy research within the U.S. Government. This support has increased significantly over the last 5 years, from \$1.2 million in fiscal year 2003 to an estimated \$13.4 million in fiscal year 2008, a greater than 10-fold increase. NIAID-supported food allergy research includes basic and pre-clinical research on the immune mechanisms involved in food allergy, research to understand the epidemiology and genetics of food allergy, and clinical studies to treat and prevent food allergy. Like all of NIH, NIAID awards grants to researchers whose investigator-initiated proposals are judged in peer review to be of high quality. NIAID also solicits research proposals through special initiatives that target particular areas of inquiry and foster collaboration within the field. These initiatives and networks include the NIAID Consortium of Food Allergy Research, the Asthma and Allergic Diseases Cooperative Research Centers, the Immune Tolerance Network, and the Inner City Asthma Consortium. NIAID also supports intramural investigators on our Bethesda, MD, campus who work on allergic diseases and anaphylaxis, including a new program focused specifically on food allergy.

In addition, NIAID supports a much larger portfolio of basic research on immunologic and allergic mechanisms that is relevant to the problem of food allergies. In fiscal year 2007, support for this broader research portfolio totaled more than \$500 million. The Institute's broad support of basic research in allergy and immunology provides a critical foundation that is advancing the field of food allergy, providing scientists with a better understanding of how the healthy immune system averts the development of allergy and of the mechanisms that contribute to allergy. Food allergy is frequently accompanied by other allergic diseases including atopic dermatitis (eczema) and asthma. The latter is an important risk factor for severe allergic reactions to food. Thus, research findings in the broader areas of immu-

nology, including asthma and allergic diseases, likely will move the field of food allergy forward.

In the area of basic research in food allergy, researchers are studying the molecular structure of food allergens and their interactions with the immune system, including the immunoglobulin E (IgE) antibodies that mediate allergic reactions to food. For example, scientists are analyzing the specific structures, called epitopes, in food allergens that are recognized by IgE antibodies. These structures—and how they are recognized by the immune system—may determine the severity of a person's allergic responses and the persistence of allergy throughout his or her life. NIAID-supported scientists also are conducting basic research on the components of the immune system that play a role in anaphylaxis, studying the molecular events that precipitate and characterize anaphylactic reactions, and conducting long-term studies of patients with food allergies.

Pre-clinical studies include the development and characterization of animal models of food allergy. Improved mouse models, which have been developed in recent years by NIAID-supported researchers, mimic many of the important characteristics of human food allergy. Potential approaches to treating and preventing food allergy are being evaluated in such animal models, as a prelude to human studies. Some experimental approaches are relying on the use of allergenic foods as immunotherapeutics, capable of eliciting immunological tolerance with repeated, controlled administration. Other investigators are treating patients with structurally modified foods that are less likely to cause serious allergic reactions, but which may still elicit a state of tolerance. The safety of one such experimental treatment, the use of bacteria engineered to produce modified peanut proteins, may eventually be tested in non-allergic adult volunteers and, if proven safe, in allergic individuals.

Very little is known about why only certain people develop food allergies. Research on the epidemiology and genetics of food allergy may provide insight into the genesis of food allergy and suggest approaches that may preempt children from developing allergies to certain foods. For example, the NIAID-supported Consortium of Food Allergy Research is conducting an observational study in which more than 400 infants who have allergies to milk or eggs have been enrolled, most of whom will lose their allergies to milk and eggs within a few years. Some of these children will develop allergy to peanuts. The study will follow the children for at least 5 years and study immunologic changes that accompany either the loss of allergy to foods or the development of allergy to peanut. Another study, the Urban Environmental Factors and Childhood Asthma Study, a project of the Inner City Asthma Consortium, is an observational study monitoring a cohort of children from birth for a number of factors, including the appearance of specific IgE antibodies to foods. This study will provide epidemiological data to address the relationship between asthma and food allergy.

The results of basic, pre-clinical, and epidemiological research have suggested a number of approaches for the prevention and treatment of food allergy. These approaches are being evaluated in several current and planned clinical trials. For example, in the United States, until earlier this year, the pediatric medicine community generally recommended avoidance of exposure to peanuts and other common food allergens during early life. However, epidemiological studies have raised the possibility that early life exposure to peanuts may lower the rate of peanut allergy. More than 90 percent of Israeli children eat a popular peanut snack called Bamba starting before their first birthday, yet the prevalence of peanut allergy in Israel is 10- to 20-fold lower than in the United States. To test the hypothesis that early exposure may prevent food allergies, the NIAID-sponsored Immune Tolerance Network is conducting a trial to determine whether feeding a peanut-containing snack to young children at risk of developing peanut allergy will prevent its development.

With regard to treatment of established food allergies, a number of trials are ongoing or in the planning stages. The Consortium of Food Allergy Research is conducting or planning several pilot trials of oral and sublingual (under the tongue) immunotherapy in egg- and peanut-allergic subjects to study safety and the ability of these approaches to desensitize subjects with allergies and induce immunological tolerance to the test allergens. In addition, the NIAID Asthma and Allergic Diseases Cooperative Research Centers are developing a clinical trial to evaluate whether, in combination with oral milk, a currently licensed drug for allergic asthma can reduce the incidence and severity of adverse effects of milk immunotherapy and facilitate the development of tolerance in patients with milk allergy.

The field of food allergy research has benefited greatly from the support and involvement of advocacy groups and philanthropic organizations. Included among these are the Food Allergy and Anaphylaxis Network, the Food Allergy Initiative, and the Food Allergy Project, each of which supports public awareness efforts, sci-

entific workshops, and/or research projects, either independently or in collaboration with NIH.

FUTURE PLANS

In March 2006, as required by the Food Allergen and Consumer Protection Act of 2004 (Pub. L. 108-282), NIAID convened the NIH Expert Panel on Food Allergy Research. The Panel reviewed basic and clinical efforts related to food allergies and made recommendations to the Secretary of Health and Human Services for enhancing and coordinating research activities related to food allergies. The findings and recommendations of the Panel were summarized in a report released in June 2007 and available at <http://www3.niaid.nih.gov/topics/foodAllergy/research/ReportFoodAllergy.htm>.

The Panel discussed the challenges that NIH faces in the area of food allergy research, including the need to expand the relatively small cadre of scientists working in this area. To address this concern, in August 2007, NIAID announced a research initiative, *Exploratory Investigations in Food Allergy*, that will support innovative pilot studies and developmental research on the mechanisms of food allergy, with a goal of attracting additional investigators to the field of food allergy research. We are particularly gratified that almost all of the applicants for this initiative are new to the field of food allergy research and that approximately one-third have not had prior NIH funding. Co-sponsors include the Food Allergy and Anaphylaxis Network, the Food Allergy Project, and the U.S. Environmental Protection Agency. NIAID expects to award grants under this initiative this month.

The Panel also identified a number of impediments, concerns, and challenges to the conduct of clinical trials for the prevention and treatment of food allergy. One such challenge is the difficulty of studying new approaches in pediatric patients, including infants. Other concerns relate to the potential for severe reactions to foods or food allergens in treatment or prevention trials and the current lack of tools to identify those at the highest risk for such reactions. The Panel recommended that Secretary of Health and Human Services direct the NIH and the Food and Drug Administration (FDA) to resolve impediments to the design and conduct of clinical trials for the prevention and treatment of food allergy. In response to this recommendation, NIH and FDA will convene a workshop next month on the design of food allergy clinical trials.

The Panel also made a number of recommendations regarding the future of food allergy research, including those related to clinical trials, epidemiology and genetics, basic and pre-clinical studies, and research resources. A number of the research activities described earlier address these recommendations. NIAID is firmly committed to implementing the remaining recommendations.

In addition to its research portfolio in food allergy, NIAID supports other activities to improve the lives of those who are affected by food allergy. For example, NIAID is coordinating the development of comprehensive clinical guidelines for the diagnosis and management of food allergy. This effort will provide guidance to clinicians, families, and patients for diagnosing and managing food allergies. NIAID will convene a Coordinating Committee in the summer of 2008 to oversee the drafting of these guidelines. The guidelines will be prepared through a two-pronged approach, including an independent evidence-based literature review and consensus opinion developed by an expert panel. More than 20 professional societies, advocacy groups, and NIH Institutes and Centers will be involved in this process.

CONCLUSION

With evidence indicating an increasing prevalence of food allergy in the United States, food allergy and associated anaphylaxis have emerged as important public health problems, particularly in children. Over the last 5 years, NIAID has substantially increased its support for basic, clinical and epidemiological research on food allergy and anaphylaxis. While much progress has been made in the scientific understanding of food allergies and in the public's awareness of difficulties in managing them, many challenges remain. NIAID is strongly committed to the goal of reducing the burden of food allergy for the millions of affected children and their families in the United States by continuing and expanding support for research to understand food allergies, by bringing new scientists into this research area, and by developing interventions for treatment and prevention.

Senator DODD. Thank you, doctor. Thank you very, very much. Those charts and graphs I think are very, very helpful and give you some sense of this.

Why do you think this is happening? What do you attribute it to? I've read the stories, read the *Newsweek* article. That was the jacket. I read everything that comes along about this, I think like most parents would. Share with us what you think is going on. Why are we getting this explosion in the number of people who are suffering from food allergies?

Dr. FAUCI. You know, the correct answer is that we don't know. There are a number of hypotheses and I know you've heard of them, but for the sake of everyone here there are, for example, the hygienic hypothesis, that as we get more public health hygiene we get less exposed to environmental microbes, as well as common things that stimulate the immune system, that the immune system is not properly trained to control aberrant reactions to things that they shouldn't be reacting to, which is the reason why people in developing nations who get exposed to things in the environment—dirt, microbes, et cetera—seem to have much less allergies in general and even food allergies.

The other is a pollution hypothesis, where by the pollutants in the air we're stimulating and activating the immune system, which then in synergy interacts with the response that you might have to a food allergen. If your immune system wasn't so revved up, it may be that you would not have that aberrant response.

Then there's things like food processing, change in food processing, presenting food to the body in a different way. We get hints of that from the Chinese, for example, who boil peanuts as opposed to what we do generally, is roasting peanuts.

Then the whole issue of: are we approaching the problem well enough, are we thinking that total avoidance is the answer, and might we by avoiding it actually have the paradoxical effect of not training the body to respond well. That's one of the studies we have, to see if high dose early exposure—a typical example of this possible hypothesis is that in Israel, where it's 10 to 20 times less food allergies than the United States, they actually expose children to a certain kind of a food called Bamba, which is a peanut candy, which they get very early in life. You would think that that would be precipitating if all things being equal, that that's the cause of these things, these early exposures. In fact, it's just the opposite, we believe.

All of these things are open to study, which is the reason why we're excited about getting more people involved.

Senator DODD. You mentioned the difficulty we have in getting these investigators. A report, a 2006 "Report of the NIH Expert Panel on Food Allergy Research" showed the fact that only 15 percent of the current NIAID support for food allergy research is through investigator-initiated awards, compared to approximately 60 percent of investigator-initiated awards for the full spectrum of NIAID-supported research.

Can you explain why that is such?

Dr. FAUCI. Absolutely. That falls exactly, Senator, into the issue that I'm trying to make. There are two types of awards. The awards are investigator-initiated, as you say, where the idea comes from the investigator, they put in an application, it competes in a peer review function with all of the other grants that come in. When a field is a hot field, when a lot of people are involved and

a lot of people are interested in it, you don't have to worry about beating the bushes to get people to send grants in. You have more applications than you know what to do with.

If you have a hot field like HIV-AIDS or certain cancers, et cetera, there's a lot of investigators around.

When you need to jump-start a field early on, what you do is you put out a request for applications and you set aside a certain amount of money to tell investigators: "Come on, we really want you to get involved." Once you get the cycle going, it then self-sustains itself. That's what we're really trying to do now, is to jump-start it so we get enough people that we don't have to go out and ask them to hand in grants; they will actually hand it on on their own initiative.

Senator DODD. Well, I hope we'll see a change in that.

Let me go back to the resources. Again, I appreciate the fact that there's been a jump from \$1.2 million in 2003 to an estimated \$13.4 million in fiscal year 2008. We're still talking about, quick math, we're talking about a dollar a person if you accept the statistics that more than 12 million people in the country have food allergies.

How much of that amount is actually being spent by NIAID versus other institutes?

Dr. FAUCI. Almost all. NIAID is the major institute in spending in food allergy. I might point out—and this by no means is an excuse for that, what is clearly obviously a relatively low amount—is that there is about \$500 million that we've invested in mechanisms of allergic responses and immunological responses, which aren't specifically coded as food allergy, but that play into understanding the mechanisms that will ultimately allow us to ask specifically food allergy-related questions.

Again I want to underscore, Mr. Chairman, that's not an excuse for not doing more in the other. There is indeed a pretty good matrix and base of research that goes into understanding immunological mechanisms.

Senator DODD. You anticipated my next question. How much of that money is actually in research?

Dr. FAUCI. It's all. Everything I'm talking about is research.

Senator DODD. It's all research.

Dr. FAUCI. It's all. Everything that comes out of NIAID and NIH is research dollars.

Senator DODD. So that \$13.4 million is really all research?

Dr. FAUCI. It's all research.

Senator DODD. And how does that compare? I'm looking, and you're right and I appreciate you mentioning, we have I think it's an estimated 1.2 million Americans living with HIV-AIDS, a serious problem obviously. I forget the numbers, but the numbers are obviously vast in excess of \$13.4 million.

Dr. FAUCI. It's \$2.9 billion.

Senator DODD. Billion.

Dr. FAUCI. Right.

Senator DODD. For 1.2 million. Again, we want to be careful here, apples and oranges.

Dr. FAUCI. Right.

Senator DODD. I'm not trying to suggest somehow that we shouldn't be making an effort there. By comparison, with 13 million people and a growing number—do you see any indication that these numbers are sort of leveling off, or do you anticipate the increase in the number of people suffering with this are going to increase? Any indication on the research you've done so far? Are we looking at a growing problem or is it one that's stabilizing?

Dr. FAUCI. Again, we don't know, and I think that's the reason why we want to wed understanding the basic pathogenic mechanisms—it can give us a better feel of what it is that's responsible for the increase. Whenever you see an increase, there's always two possibilities: either we're recognizing more of something that was always there or it's actually increasing. I think it's both, but I think—I don't think—I know it's unquestionably increasing, and the question is, in order to do something about that we've got to figure out what the fundamental mechanisms are, are any one or more of those hypotheses that I mentioned correct, and if so should we be able to use our fundamental knowledge of the pathogenesis to make those numbers go down.

A typical example, Mr. Chairman, is that if something like an earlier exposure to an allergen in a population in which X percent are predisposed genetically or otherwise to get allergy, if you then do that would you then negate a certain percentage of those from progressing on to allergy, the way we suspect might be going on, for example, in Israel or in China, where they process the food differently.

We need to understand the basic pathogenic mechanism and then I'll be able to with confidence answer your question that now we know why it's happening, we're trying to do something about it.

The pollutant hypothesis, that's something that as pollution keeps going, if in fact that is contributing in some manner or form to that, I think that's going to follow the curve of how bad pollution is in certain cities.

Senator ALEXANDER. You talked about jump-starting an effort to attract more investigators. What amount of money would it take to do that?

Dr. FAUCI. Well, you know, it's interesting. Right now it doesn't take as much as you would like to ultimately have. Let me explain what I mean by that specific answer. If you said, I'm going to put in several hundreds of millions of dollars into food allergy right now, we don't have the investigators around to spend that money well. We could double what we do right now and get people interested in it, and maybe even more than that. Once you do that, you'll have an increase that would almost be exponential as opposed to linear.

Quite frankly, Senator Dodd mentioned the whole idea with HIV, where we're spending \$2.9 billion now because of the—for the scope of the problem. Again, we don't want to compare apples and oranges, but in the beginning we had very few investigators who were interested in studying HIV. Once we got a cadre of people, then the amount of funds that we could meaningfully spend went like this. In the beginning the increases were modest to get people involved in it.

I think that same sort of phenomenon on a lesser scale, obviously, we'll see with training people for doing research with food allergies.

Senator ALEXANDER. Double means twice \$13 million?

Dr. FAUCI. Yes.

Senator ALEXANDER. The \$13 million is the number that you're spending.

Dr. FAUCI. The \$13 million is what we're spending right now.

Senator ALEXANDER. This would be basically to attract investigators to a "hot topic," to say, bring us your best ideas.

Dr. FAUCI. Bring us your best ideas.

Senator ALEXANDER. We can have a peer review examination to see which are the most promising ideas—

Dr. FAUCI. Exactly.

Senator ALEXANDER [continuing]. And send them off and see what comes of it.

Dr. FAUCI. Right, exactly. Also, it's a signal to young people who are coming out of their residencies, who are coming out of their fellowships, is what is a field that's attracting interest, where I know there's a commitment at every level, at the level of the administrations, the Congress, and the scientific community and the constituency groups, that we want to go after that.

When they sense that, they're not stupid. When they need to make a decision about where they want to go and they see that this is a field that's going to be supported, because even a field that doesn't attract a lot of interest, once you start probing and you start understanding the pathogenic mechanisms that's what excites young investigators, that can we probe and really figure out what's going on, as opposed to a field that looks like it might be a dead end, that nothing really exciting is happening.

The money's going to do two things. It's going to open up the doors of knowledge, but it's going to be a good inducement for young people to get involved in the field that they know people like you and I are interested in pushing the envelope on.

Senator ALEXANDER. This would be an appropriation to NIH for this specific purpose?

Dr. FAUCI. Yes.

Senator ALEXANDER. It seems the allergy—this phenomenon seems to have just come out of the blue to most people over the last 10 years, though not to the families that have been individually affected, but to the public at large. This is new to the experience of most people and an alarming thing.

I had to telephone a friend, whose name I won't mention, who I appointed judge 25 years ago when I was governor, and he and his wife went out to a reception at a friend's house and she had one of these allergies and ate the wrong thing and died that night because of it.

Obviously these have been—the peanut allergy and others—around for a while, but it does seem like there is an explosion of it that we need to understand.

Let me now go to the other area. It seems like the two areas we're focusing on are enough money and the mechanism for the research to try and understand what has happened, so we can figure out what to do that might immunize or prevent it. The other side

is awareness, and we're talking about schools. You say in your testimony there's a particular problem for children in school lunch rooms and other social settings where others may minimize or fail to understand the seriousness of the allergy.

We've got 105,000 public schools. In your experience, what's the most effective thing we could do to help those in school lunch rooms understand the seriousness of this?

Dr. FAUCI. I think all one needs to do is to look at what the Chairman himself has been trying to do with his legislation, and that is to get the kinds of guidelines and in many cases hopefully even mandatory guidelines so that when people who go to school, nurses in school, teachers in school, understand this problem right up front.

It's amazing—and even not only in schools, but even in some emergency rooms, to educate people. If someone comes in—and I've seen this myself. It's scary to see. Someone will come into an emergency room with an anaphylactic reaction to what is apparently or possibly, maybe highly likely, a food allergy, you treat the anaphylactic reaction, the person does well, and you go out, and you don't inform them that they need to get under the care of a physician to investigate what the source of that anaphylactic reaction is, what one can do to actually prevent it from occurring again.

It's very heavily steeped in the kind of education and pursuing of guidelines that the chairman himself has been trying to push.

Senator ALEXANDER. I'm not trying to be rude. We have 1 minute before the next vote.

Senator DODD. We'll come right back, take a recess for 5 minutes and we'll be right back. Thanks.

[Recess.]

Senator DODD. The committee will come back to order. Thank you, doctor, very much. We won't keep you a great deal longer.

Senator ALEXANDER. Mr. Chairman, I might have missed the last part of his answer. He was saying nice things about the guidelines that you're suggesting. What I was trying to make sure I understood were the most effective things that we could do here, that would take into account that the 105,000 schools are different schools in different places—and my old bias as governor is that decisions made closer to the child usually are better decisions, so to get your advice about how Federal guidelines interact with State—might interact with State efforts to encourage an awareness in the lunch rooms of food allergies, what would your advice be?

Dr. FAUCI. My advice would be to pursue the model from the Federal—we all agree, those of us who work at the grassroots level, that it's best to have it at that level. But not infrequently in guidelines that I've been involved with in a variety of diseases, that when the local level are looking for guidance they don't like to be dictated down from above, but they do use that as a model for the things they incorporate locally.

That's why when I see legislation that is talking about setting some guidelines that could serve as standards locally, that even if that isn't something that some of the localities would embrace the fact that you've set the model, they very often very, very closely draw from that model.

In that respect, the kinds of legislation that I mentioned, Senator Dodd's bill that he has proposed and other such guidelines, are going to be very important.

Senator ALEXANDER. Thank you.

Thank you, Mr. Chairman.

Senator DODD. Thank you, very much.

Let me just pick up. Some of this you've already addressed—I was thinking, going over the questions coming back, that you mentioned Israel, you mentioned China. I've always read it as developed or industrialized countries versus less well developed, although Israel is certainly the former, although we learned this morning about China and the stories about how many gaps exist between poverty and wealth in the country—and I've always drawn, when I've read those stories, my assumption has been, going back to the first answer you gave to the question of why are we seeing more of this, and it's the—I'm not going to be terribly technical in this, but the idea that we're far more sanitary today.

In fact, Jackie and I were talking to a woman the other day who is about to have a child in June, and we were talking about this subject over dinner. She said her gynecologist was recommending she drink tap water and not bottled water. I've always assumed that the notion of industrialized versus developing countries had to do with the quality of sanitation in a lot of areas, where we're less exposed to certain bacteria, and therefore we don't build up the natural immunities to some of them.

You seem to be suggesting something more than just that.

Dr. FAUCI. No, actually there are a couple of things. It so happens that parts of China are a developing country, but there happen to be just customs in that country of processing. It has to do with two things. Some countries, be they developing or not, might process food a little bit differently, that could give an unrecognized difference in the allergic response.

The issue of low-middle income and less hygiene has to do with the very powerful hygienic hypothesis, that has not necessarily been proven, and the hygienic hypothesis is exactly what you say, Mr. Chairman, that you have children running around exposed to a lot of environmental antigens from the very, very beginning, so their immune system develops what's called a regulatory mechanism, so that when they get confronted with something that they may be predisposed to have a hyper-reaction to, they have a lot of control mechanisms in place.

If you are pristine in your hygiene, you prevent the immune system of infants and very, very young children from getting that type of normal bombardment of antigens, and then when they do see something like a food that they may be predisposed to have an allergic reaction to, instead of having a sub-clinical or barely recognizable one, they may have a severe one.

Senator DODD. Let me jump to the issue of investigators. Again, I think I sort of got a chicken and egg answer, I thought, from you. The more research money you put out there, the more investigators you get. Is that really what needs to be done here more than anything else, or is there something else we can be doing to attract more investigators to move into this area?

Dr. FAUCI. There's both. There's no doubt that the investigators go where the money is. If they see a field that's really clearly underfunded, they are not going to be associated with senior people like Dr. Sampson, who actually are thriving in that environment because there's money there for good ideas. If there's no money for good ideas, you're not going to have young people—it is a chicken and egg hypothesis, Mr. Chairman, because if you don't have money to attract the young people into training programs like that, then you're cutting off the supply of new ideas, because, although there are a lot of brilliant older people, some of the crazy, off-the-wall ideas come from very young people who are early on and are not jaded by a bunch of failures, and they say, "why don't we try this," and all of a sudden you have a really brilliant hypothesis that's being formulated.

So it is chicken-egg.

Senator DODD. What sort of coordination is there between the FDA and what NIAID is doing?

Dr. FAUCI. We communicate and interact with FDA all the time, particularly when we are in the process of a clinical trial to test a new intervention. We go right from the beginning. Unlike some of the old days, where you would do a clinical trial and then you'd get a result and then you'd present it to the FDA, almost for the first time they're seeing what your ideas were, what your hypothesis was, now we start with the FDA right from the very beginning.

Senator DODD. They've been cooperative. Are they doing any work independently that you're aware of?

Dr. FAUCI. Very much so. The FDA does some research. They do it in areas such as diagnostics and other types of research. Our relationship with the FDA is quite good.

Senator DODD. What has NIH done with regard to that 2006 expert panel, and the recommendations made by the panel? Has NIH taken any specific steps on these recommendations?

Dr. FAUCI. Oh, a lot, yes. The expert panels have made a number of recommendations that we have been in fact implementing. Particularly an important one is to set up a panel to look at the safety of certain types of clinical trials. We are faced with an interesting, risky issue vis-a-vis clinical trials, because when you have a disease that isn't as acutely and dramatically life-threatening as anaphylaxis and you're going to try an intervention, not infrequently you'll test one medication against another or one intervention against another, and if you are incorrect there's no dire consequence to the patient because it's easy to take care of, it's nonlife-threatening.

When you have a disease like anaphylaxis and you're trying to see if desensitization or early challenge with a high dose versus avoidance, and you're looking at that question, which is an absolutely critical question, what happens if you're wrong? You can trigger a kind of anaphylactic reaction that could actually, and hopefully wouldn't happen but sometimes does, kill the subject in the clinical trial.

The panel that you're referring to has now gotten together a group to very carefully set some guidelines about the kinds of safety precautions that must be built into a clinical trial if you're going to take the safety of young children or anybody into risk. Even if

the greater good is to get knowledge that might help thousands, you still have to worry about the few that are in the clinical trial. And we're very heavily involved in that.

Senator DODD. I'm going to be careful not to quote Dr. Sampson, but I heard him yesterday talk about testing we've done with animals in these areas, and it's been rather exciting and positive in terms of—I can't recall whether he talked about—whether we actually tried higher dose exposure and how that worked or not.

Dr. FAUCI. It's the hypothesis that we're all cautiously excited about, because whenever you're doing biological experiments there's often a lot of failures. It's trying to test if maybe the original paradigm needs to be stricken down and instead of compulsive avoidance when you have the suspicion that there might be a food allergy, to actually give the child a higher dose of it very early on. We used to refer to that as high zone tolerance, namely you bombard the body with something and it learns to cope with it because it develops regulatory mechanisms and it doesn't bother them after that.

Senator DODD. Let me come back to the question I raised with you earlier, just addressing asthma as well in this context. I asked you about why this seems to be on the rise and I thought I understood your answer here. Is it unusual for noninfectious diseases to increase with such rapidity? We're also seeing the rate of asthma and other allergic and immunological disorders. Last week there was World Asthma Day and, looking at some numbers, more than 16 million adults, and nearly 7 million children have asthma, leading to nearly 1.8 million emergency department visits and half a million hospitalizations each year.

Again, partly we're better able to detect it. Also—are there other examples historically, talking about noninfectious diseases, such as these, where we've seen a rapid increase?

Dr. FAUCI. Well, the increases are generally not rapid. They are significant and noticeable, and then once they increase people start looking for them more and then you get the added issue of noticing things more that you wouldn't notice.

What we're seeing is a combination, not only with this—and I'll give you an example in a second—that there is clearly more of this, and as there is more of it and we do things like we're doing today, people generally are going to be more aware of it.

Now, when you have a cataclysmic thing like anaphylaxis, everybody notices anaphylaxis. You can't say, "well, there was a lot of anaphylaxis going around, but we didn't notice it." You notice anaphylaxis when it's there. So that's not the kind of thing.

There are, for example, some noninfectious diseases, some of which have to do with environmental or other things that are related to behavior. Some things environmental we can't help. We did an asthma study in our Inner City Asthma Consortium where it was very, very clear that young children, particularly minority children living in poorly maintained projects in which there were cockroaches, etc, all of a sudden we were seeing an incredible rise in that, mostly because of the crowding there.

When you have air pollution, which stimulates an organ system such as the lung to get more hyper-irritated, that is something that's noninfectious. There's the eating habits in this country which

are leading to the epidemic of obesity. That's not infection. There is the whole smoking problem that we're just starting to see now—I know, I'm sure you read about it most recently—that the life expectancy, particularly among women, that was going up and up and up, is now starting to level off and even come down. We're starting to see the late effects of the women having more freedom to go and do what they want to do in the sense of society and smoking more. Thirty years later, you see lung cancer and heart disease in women going up. That's not an infectious disease, but something changed. What changed? Women smoked more decades ago.

There are five or six or seven examples of that.

Senator DODD. How about genetics?

Dr. FAUCI. You know, genetics change, but they change over generations and generations, and when you get mutations and things like that.

There are things—and it also relates a bit to the kinds of things that we're studying with food allergy that are—now that we have the genome sequence, we now know all of the different components of it, and there are things called single nucleotide polymorphisms, or SNPs, and that's just a big word to mean that in a stretch of nucleotides—that's a gene that you might have and I might have, the same gene—mine is a little bit of what's called, has a change or a polymorphism. It's a little bit different, which means that I might have a propensity to anything from diabetes to schizophrenia to bladder cancer or what have you, that even though the gene is very similar between you and I, because of that polymorphism I have a propensity to that.

When we learn a lot more about that, we'll be able to predict, prevent, and preemptively do things about certain diseases. Certainly something like a food allergy may in the future—we can't do it now; we don't have the level of sophistication of what the genetic propensity is. Once we get those kinds of things that are easily doable relatively cheaply, we'll be able to tell a family, there's a reasonable chance that this might happen, so you better be on the guard for that.

Senator DODD. How about outgrowing food allergies? We've heard certainly in talking to our pediatric allergist that there are certain foods where there's a good chance Grace will grow out of her allergies to them, and others probably not. What percentage—you mentioned earlier—I think you did, anyway—that many would outgrow a lot of these and that's the good news. Do you have any numbers at all?

Dr. FAUCI. No. If you talk about egg and milk allergies, a fair percentage if not the majority of people will outgrow that. If you look at peanut allergy, it's different. If you look at crustacean allergy, there are adults who, as you say, the sad cases, which I've seen myself, if someone goes into a restaurant and thinks they're getting X soup and they're really getting soup with a little bit of contamination, and they get anaphylactic reaction. Adults clearly get that.

So crustacean and peanut allergies generally not as much as something like egg or milk, which you can grow out of.

Senator DODD. Well, this has been terrific. You're very patient, too. Thank you immensely.

We'll leave the record open. We may have some additional questions to submit to you. It was very, very helpful, and thank you for your kind comments about the proposed legislation as well. One of the things we do in the bill—the House passed a bill. The one difference we have in our bill are the grants, \$30 million nationwide for schools to apply. It's really more the funding and technical assistance in putting these guidelines in place that school districts would like.

The money goes directly to the school district, not to the State, going to your point earlier. This would bypass the administrative costs in the State, where that money can be lost very readily.

We'll hear in a moment from the Supervisor of School Health for West Haven, CT, where again I don't think there was any money really available from the State. There may have been. Nonetheless, because there were State guidelines it really was a great help and assistance.

Dr. FAUCI. Thank you very much, Mr. Chairman, Senator Alexander.

Senator DODD. Thank you. Glad to have you with us.

Let me invite our second panel to join us, and I appreciate their patience as well. Teresa Walters, our first witness, is currently living in Aurora, CO, with her husband Rick and her 12-year-old stepson. She's with us today because 7 years ago Ms. Walters learned firsthand how tragic life-threatening food allergies can be. Her son Nathan suffered from a known peanut allergy. He was given a peanut butter cookie while on a class field trip and had an anaphylactic reaction. By the time medical attention was administered, not unlike your story, Lamar, she lost Nathan, and that's how quickly this can happen. I'm very grateful to Ms. Walters for being here today with us, to share with us her story. She's a committed advocate for research and educational programs so that other parents don't have to experience the same tragedy that she did. We thank you immensely for being here with us today. You're very gracious to come and tell the story. It's not easy, but it means a lot. If we can use this forum as an educational tool, then your presence here in some small way will make a big difference in other people's lives, and I hope you'll appreciate that. So I thank you for coming to be with us.

Dr. Hugh Sampson, you've already been sort of introduced by Dr. Fauci. He's called you a superstar. My introduction is modest by comparison, doctor. He is one of the leading experts in this area, a professor of pediatrics and chief of the Division of Pediatric Allergy and Immunology, Director of the Jaffe Food Allergy Institute at the Mount Sinai School of Medicine, New York. He's also President of the American Academy of Allergy, Asthma and Immunology. We thank you immensely, doctor, for being with us.

Ms. Donna Kosiorowski is someone I know. We spent Monday together. She is from West Haven, CT. She is the Supervisor of School Health in West Haven, CT. She is also the Connecticut Director of the National Association of School Nurses.

Ms. Kosiorowski started her nursing career in Bridgeport, CT in 1971. For 23 years she's been a member of the educational team

of Connecticut public schools. She and her husband, a retired State trooper, reside in Shelton, CT. As I previously mentioned, Ms. Kosiorowski and her team graciously hosted me on Monday at the Washington Elementary School. I was very impressed with what a great job they're doing at that school in this area.

Do you want to introduce Colene?

Senator ALEXANDER. Sure, I'd like to.

Colene Birchfield and her family live in Ooltewah.

Senator DODD. I couldn't pronounce the name of the town anyway.

Senator ALEXANDER. It's a good Cherokee name, Ooltewah, TN.

She's a music teacher in an elementary school. She's an operatic singer or has been, and choral music, the daughter of an Air Force colonel, and we are delighted to have her here today to help us understand food allergies.

Thank you.

Senator DODD. Thank you all very much. We'll begin with you, Ms. Walters. Thanks for being with us.

STATEMENT OF TERESA WALTERS, PARENT, AURORA, CO

Ms. WALTERS. Chairman Dodd, Ranking Member Alexander, and distinguished members of the committee, thank you for inviting me here today. It is also a pleasure to address this panel that contains my home State Senator from Colorado. This committee is doing a great service to the millions of families around the country who have children with life-threatening food allergies.

I'm especially appreciative of Senator Dodd's efforts to champion S.1232 and provide greater resources for schools who are struggling daily with the challenges posed by food allergies. You've already heard some information about childhood food allergies and the speakers that follow me will share their perspectives as doctors, nurses, teachers, and parents of food-allergic children. You've heard food allergies referred to as life-threatening and you may consider that overly dramatic. After all, a lot of medical conditions can be life-threatening if they're not treated properly. I'm here today to share my perspective as a mother who found out firsthand what "life-threatening" means.

Almost exactly 7 years ago, my son Nathan died from a severe allergic reaction to peanuts. He was 9 years old. Nathan's third grade class in Washington State was scheduled to go to a local farm along with two additional third grade classes. By the time the bus got to the farm, it was close enough to lunch time that the school lunches were passed out. Lunch consisted of a peanut butter and jelly sandwich, trail mix with peanuts, and a peanut butter cookie. A special lunch was supposed to have been ordered for Nathan, but it wasn't. He received the same lunch as the other kids.

When he realized what was in his sack lunch, he returned the sandwich and trail mix to his teacher and told him that he couldn't have those things, he was allergic to peanuts. His teacher commended his awareness and Nate returned to his friends thinking that he could eat what looked like a sugar cookie. Nathan didn't realize that he was eating a peanut butter cookie and didn't recognize the taste.

When he was about halfway through, he commented to his friends that his tummy felt funny and alerted his teacher that he didn't feel well. His teacher recruited the assistance of a parent volunteer who was also a nurse practitioner to sit with Nathan on the bus so the other kids wouldn't have to miss out on their field trip. Nathan had with him his inhaler and his EpiPen.

Nathan sat on that bus for 2 to 3 hours. When the field trip was over, it was decided that a parent would drive Nathan home rather than back to school; the nurse practitioner would go along. Witnesses say that Nathan was unable to walk unassisted at this point and looked like Elephant Man. By this time he had been given a few sips of Sprite and his inhaler. He was laying down in the back seat and Nathan finally left the farm, approximately 3 hours after ingesting a few bites of cookie.

A few minutes into the drive, the nurse practitioner asked the parent driver if she thought it was advisable to give Nathan his EpiPen. The other parent didn't know what that was, but recognized that Nathan was in serious trouble and quickly pulled into a fire station a few miles away from the farm. Nathan had stopped breathing and his heart had stopped beating by now.

One of the women ran into the fire station and asked if oxygen was available. Most of the firefighters were out of the station on training, but one of the volunteer firefighters was there. He called 911, followed the woman to the car, and he was the one who finally administered Nathan's EpiPen. He also began CPR.

Less than 1 minute later, paramedics arrived and took over life-saving efforts while racing to the hospital. I am told that the doctors worked on him for over an hour, past the point of any hope.

My understanding is that Nathan might have survived if he had been given his EpiPen, especially considering how close emergency medical care was. I know he would have survived if his health care plan had been followed, if his school had received additional training on the severity and risks of food allergies.

As I'm sure you can imagine, the death of my son was simply devastating. It was a year before I could even think about going back to work and not a day goes by that I don't think about him and wonder what he would be doing now if he were still here with us. I live in Colorado now and I remarried a year ago.

Fifteen years after being adamant about not wanting to go through the terror of possibly having another child with severe food allergies, my husband and I recently found out some wonderful news: I am 4 months pregnant with our first child together. We're doing all the usual pregnancy things—eating right, taking care of myself, making sure I get a lot of sleep. No doctor can tell me what I can do to make sure that my daughter does not develop a severe food allergy like Nathan did. The doctors simply don't know why Nathan had a food allergy and they can't tell us why so many more are developing these life-threatening allergies every year.

I appreciate what this committee is doing today to focus attention on the issue of life-threatening food allergies. This issue is not going away. There are a lot of important public policy issues facing this Congress and our Nation. Focusing on childhood food allergies needs to move up on our priority list. I urge you to do what you

can to make sure that no parent has to endure what Nathan's dad and I have.

Congress has the power to increase research funding, to protect children in the school environment, and to raise public awareness so that food allergies are treated like the life-threatening serious medical condition that they are. Much more needs to be done.

Thank you.

Senator DODD. Thank you, very, very much, Teresa; very, very compelling testimony. You're a courageous woman. Good luck. I'm very excited for you.

Let me turn to you if I can, Colene. Then we'll come back and, doctor, I'm going to ask you to be our last witness, so we can hear these other people talk and then we'll hear from you.

Colene.

**STATEMENT OF COLENE BIRCHFIELD, PARENT,
OOLTEWAH, TN**

Ms. BIRCHFIELD. Good afternoon, Chairman Dodd, Ranking Member Alexander, and distinguished members of the committee. It is my privilege to appear before my home State Senator from Tennessee today. I am thankful to the committee for taking the time to address this alarming national children's health issue. I would also like to express my support for Senator Dodd's bill, S.1232, and applaud the bill's focus in providing our Nation's schools with the necessary resources to protect children who suffer from life-threatening food allergies.

When people hear the word "allergy" they usually think of a runny nose, watery eyes, or sneezing. As I learned when my son was 3 months old, life-threatening food allergies are something very different. Ryan was given milk formula and immediately began showing signs of an anaphylactic reaction. Within minutes he was covered head to toe in hives, was vomiting, and looked pale.

We rushed him to the emergency room. With Ryan being so young and it being the height of flu season, the ER told us it was likely the flu and to just take him home and feed him like normal. It wasn't until his second reaction that we learned a milk allergy was the cause.

We spent the next several months educating ourselves as much as possible how to live with food allergies. We thought we had things covered, only to find out at about 10 months that Ryan was also allergic to egg.

Time is of the essence with any allergic reaction, precisely because there is no way to know the severity of a reaction in advance. We learned this the hard way. We are Ryan's own parents and we almost waited too long to seek treatment for him. When he was 6 years old, Ryan had contact with both milk and Bermuda grass, to which he is also severely allergic. Contact with these allergens caused an anaphylactic reaction and it wasn't immediate. Ryan came in from playing outside and just said he needed to sit down. He looked pale. We initially thought he could just be tired. We sat him down, and he immediately started coughing. We gave him Benadryl, as we thought he was starting to have a reaction.

Within a couple of minutes, Ryan started sneezing uncontrollably and could hardly breathe. We have a peakflow meter with which

to test his breathing. When Ryan is healthy his peak flow is at 225. At the time of his reaction he could barely hit 25.

At this point we decided we had to give Ryan the epinephrine. While my husband injected Ryan, I called 911. Epinephrine saved our son's life that day. We spent the night in the ER and came home more afraid than ever, but in a way also empowered that we had been able to handle the situation.

Then I thought, if it took me, his mother, that long to react, how long will it take if the reaction happens at school? Do educators and school staff know enough to be able to handle such a life-threatening situation in a timely manner? What would the kids in his classroom do? Consider the teacher, babysitter, or sports coach who now needs to distinguish between the common cold and a life-threatening allergic reaction.

Efforts to protect our children in school and other social settings are very important. However, what we need more than anything else is research to find a cure for life-threatening food allergies. Ryan participated in an exciting research study based at Duke University Medical Center in North Carolina. On each visit Ryan was given small amounts of milk protein, exposing him to the very thing to which he is deathly allergic. The hope was that over time he would build up a sort of immunity—they call it de-sensitization—and would be able to tolerate milk later in his life.

The first visit caused an anaphylactic reaction almost immediately. The doctors and nurses were very well prepared, but it was still frightening.

I was asked by a friend who has a child with a peanut allergy how I could sit there and purposely cause my son to have that reaction. My answer is simple: How could I not afford him the opportunity for a lifetime without the risk of this type of reaction occurring again? We are willing to subject our son to this kind of risk because he faces a greater risk every single day of his life simply by living in a world filled with foods that can harm him.

Our participation in the Duke study is a good example of just how desperate parents of food-allergic children are to find any kind of relief for our children. Research is our only hope for a long-term solution to these deadly allergies. There's no distance I wouldn't travel for the possibility of alleviating the daily risk Ryan faces. The old saying "No risk, no reward" is how I feel about the research. There's never a guarantee that these research studies are going to cure my child, but how could I not afford him the opportunity to try.

There's currently no treatment for life-threatening food allergies. Instead, children and their families must maintain a constant level of vigilance to avoid any kind of contact with the allergenic food. My child is allergic to milk, egg, and peanuts, and avoiding these staples of the American food supply is a constant struggle.

When people hear that a child has a food allergy, they often only look for that main word, i.e. "milk" or "peanut," on the ingredient list to tell whether a food includes that allergen. What they don't realize is that an allergy to milk, for example, means that the child cannot come into contact with any food containing any one of the many milk proteins that exist. If you don't read the label correctly your child's life could be at risk.

Mitigating risk for an infant is far simpler than when they enter the school system. My personal experience with schools is that the focus is primarily on peanut food allergies. While I am grateful that there is some awareness of the impact of a peanut allergy in a social or public situation, I think it's important for schools to understand that the potential for a life-threatening reaction is also present for those with other food allergies.

We also found that each school, regardless of whether they are in the same county, has their own guidelines for how to handle children with food allergies in a social setting. When registering my children for our current schools, I found out that the protocol is to lock the medication in the nurse's office. All the staff members are trained to use an EpiPen, but in the time it would take for a staff member to go to the nurse's office, unlock the medication, and bring it to him, Ryan could die.

The school lunch room poses a host of other challenges. When Ryan entered school there was another child enrolled who had a severe peanut allergy and the school accommodated that child by allocating a peanut-free table. I was told that Ryan could and should sit at the peanut-free table. While the school saw this as a safety precaution, Ryan is allergic to more than just peanuts. He was now sitting at a table with a child who certainly wouldn't have peanuts, but did bring Cheetos and egg products daily to the table and was sitting within inches of Ryan. This solution didn't help mitigate the risk for Ryan and it separated him from his own class. That is why it's so important to educate schools that one-size-does-not-fit-all when it comes to food allergies.

Each and every day Ryan is placed in scenarios beyond his or our control. Children like Ryan are vulnerable to allergic reactions not only at school cafeterias and restaurants, but in any public setting, from birthday parties to an afternoon spent at a friend's house.

As children grow up they are going to test boundaries and push limits. It's a natural part of their maturation process. With a food-allergic child, the teenage years can be particularly frightening as the kids struggle to fit in and prove their normalcy. One of my greatest fears is that my son will play down or try to hide his allergies from his peers out of a desire to not want to be different. If the people around him do not understand his allergies, they can't help him in an emergency situation.

You, members of the U.S. Senate, can help my son and millions of other children like him. Establishing Federal guidelines and resources for the management of food allergies in schools is essential to protect our children who suffer from this life-threatening medical condition. There are only a handful of research centers like Duke around the country that are currently doing any kind of food allergy research.

We have personally been forever affected by this research. As of November 2007, because of Duke's research on milk de-sensitization, Ryan is able to tolerate milk without reaction. We are a unique glimpse at what can be accomplished. Much more research can and needs to be done. We need new research studies, more researchers and doctors investigating the disease, and funding to allow the best scientific minds in the field to find a cure. We need advocates for our children to educate the public on just how serious

this disease is and to urge the entire community to cooperate in the vital mission of keeping our children safe.

Like any parent, I simply want my child to have the opportunity to grow and flourish in his life and to reach his potential without limitations. On behalf of Ryan and the millions of other kids just like him, I thank you for your consideration of this vital funding need. Please understand that supporting these efforts will truly make a difference forever in many families' lives.

[The prepared statement of Ms. Birchfield follows:]

PREPARED STATEMENT OF COLENE BIRCHFIELD

Good afternoon Chairman Dodd, Ranking Member Alexander and distinguished members of the committee. It is my privilege to appear before my home State Senator from Tennessee today. I deeply appreciate the opportunity to help the committee gain a greater understanding of the personal difficulties that food allergic children and their families face every day. The number of children suffering from life-threatening food allergies is dramatically increasing nationwide, and I am thankful to the committee for taking the time to address this alarming national children's health issue.

As an educator—I teach music education to elementary school children at Apison Elementary School in Ooltewah, TN—I would also like to express my support for Senator Dodd's bill, S. 1232, and applaud the bill's focus in providing our Nation's schools with the necessary resources to protect children who suffer from life-threatening food allergies. Senator Dodd's bill, and the committee's recognition of the importance of childhood food allergies, is encouraging, but there remains much to be done in the effort to prevent and cure food allergies.

When people hear the word "allergy," they may think of a runny nose or the sniffles. As I learned when my son Ryan was 3 months old, life-threatening food allergies are something very different than hay fever—and parents like me literally fear for our children's lives every day because an allergic individual's reaction to food can be so severe. Probably the scariest aspect of an allergic reaction to food is that each reaction can manifest in a different way. While one reaction might begin with a rapid succession of sneezing, another reaction may begin with lethargy, or hives. It's difficult enough for a parent to sometimes realize that their own child is having a reaction. Imagine a teacher who now needs to distinguish between the common cold and an allergic reaction. Our experience has been that many teachers just haven't been given the proper amount of education to understand how to identify a reaction and then how to treat one.

At 3 months old, Ryan was given milk formula and immediately began to vomit. Within minutes, he was covered head to toe in hives. Without hesitation, we took him to the emergency room. With Ryan being so young, and it being the height of flu season, the ER told us it was likely the flu and to just take him home and feed him like normal. Since I was mostly breast feeding at the time, it took probably another week before Ryan was fed another formula bottle. At that time, he reacted in the exact same way. We again rushed to the ER. This time, the doctor confirmed that a milk allergy was the likely culprit. Ryan needed to stay in the ER for several hours and be monitored to ensure a secondary reaction didn't occur. My husband and I were overwhelmed, as neither of our families had any members with food allergies. We spent the next several months educating ourselves as much as possible how to live with food allergies. We thought we had things covered, only to find out at about 10 months that Ryan was also allergic to egg. We had fed him a jar of baby food that contained egg. This time, Ryan first swelled up around his mouth and broke out into hives. We recognized this reaction, even though it started a bit differently and immediately gave him the Benadryl. Thankfully, he had only had a bite and we were able to contain that reaction at home. It wasn't until he was a year old that Ryan was finally able to be formally tested for food allergies. The tests confirmed that he was severely allergic to both milk and egg. With Ryan now eating table food, we sprung into action to educate everyone around us. We carried cards that contained key words to identify the proteins for egg and milk that would help us with reading ingredients. Often times, we find that when people hear that a child has a food allergy, they only look for that main word (i.e., milk or egg) to tell whether a food includes that allergen. What they don't realize is that an allergy to milk for example, means that the child cannot come into contact with any food containing any one of the 19-some odd milk proteins that exist. When reading labels, we must be diligent to look for all the variations of these protein words.

There is no “treatment” for life-threatening food allergies. Instead, children and their families must maintain a constant level of vigilance to avoid any kind of contact with the allergenic food. My child is allergic to milk, egg and peanut and avoiding these staples of the American food supply is a constant struggle. Here’s an experiment you can try at home—go to your pantry and try to find even five foods that do not contain milk, egg or peanut. Now imagine that if you didn’t read the label correctly, your child’s life could be at risk. It is heart-wrenching from a parent’s perspective to know that even with a high level of individual and parental responsibility, my child could still be endangered by a well-intentioned but uneducated teacher, caregiver, sports coach or even a server in a restaurant.

As you can imagine, mitigating risk for an infant is far simpler than when they enter the school system. When Ryan began pre-school and then grade school, we were faced with a whole new world of complications for managing his medical condition. While some school systems have a broad program for handling medication, many individual schools have discretion to develop further, their own protocol for handling individual situations. My personal experience with schools is that the focus is primarily on peanut food allergies. While I am grateful that there is some awareness for the impact of a peanut allergy in a social/public situation, I think it’s important for schools to understand that the potential for a life threatening reaction is also present for those with other food allergies. When registering my children for our current school, I was told that the school nurse is only in the building 2 days/week. This school’s protocol is such that they lock medication in the nurse’s office. All staff members are trained to use an EpiPen, of which we were thankful. The problem, as I explained to the staff, was that in the time it would take for a staff member to go to the nurse’s office, unlock the medication, and bring it to him, Ryan could die. Oftentimes, I get looked at and even remarks that I am being overly dramatic. They fail to realize that the rapid progression of anaphylactic reaction is a clearly documented medical emergency and should be treated as such. I insisted that Ryan needed to have the medication with him at all times. Time is of the essence in the event of any reaction. Going from a mild to a severe reaction can take seconds. I asked the school how they handle the lunchroom for children with allergies. This was the first year that our school has had a child with food allergies. There was another child enrolled who has a severe peanut allergy and the school accommodated him by allocating a “Peanut-Free” table. There is very limited space in the cafeteria, so this was the only exception made. I was told that Ryan could and should sit at the peanut-free table. While the school saw this as a safety precaution, I saw it as just as large a risk as if Ryan were integrated with all the other kids at any other table. The reason being, Ryan is allergic to more than just peanuts. He was now sitting at a table with a child who certainly wouldn’t have peanuts, but did bring Cheetos and egg products daily to the table and was sitting within inches of Ryan. This solution didn’t help mitigate the risk for Ryan and it separated him from his own class. I will never feel entirely comfortable with the cafeteria situation, but I do know that I’ve educated the students in Ryan’s class enough that they truly look out for him at lunch. Ryan now eats lunch with his class. He brings a “placemat” to put his food on, as the tables just get wiped off and not washed. Ryan’s teacher delivers his medication to the lunchroom with Ryan each and every day.

As I said earlier, time is of the essence with any reaction. We learned this the very hard way. I share my story of Ryan’s anaphylactic reaction to everyone who is willing to listen. We are his parents and we almost waited too long. Ryan had what one ER doctor we saw called a “perfect storm” reaction. He had contact with both milk and Bermuda grass, to which he is also allergic. Contact with these allergens caused an anaphylactic reaction. Ryan came in and just said he needed to sit down. He looked pale. We sat him down and he immediately started coughing. Now, Ryan had been playing outside, so we initially thought he could just be tired. Well, only seconds passed and we decided we better give him Benadryl, as we thought he was starting to have a reaction. Within a couple of minutes, Ryan started sneezing uncontrollably and could hardly breathe. We have a peak flow meter with which to test Ryan’s breathing. When he is healthy, Ryan’s peak flow is at 225. At the time of his reaction, he could barely hit 25. At this point, we decided we had to give Ryan the epinephrine. While my husband injected, I called 911. Epinephrine saved our son’s life that day. We spent the night in the ER and came home more afraid than ever, but in a way, more empowered that we were able to handle the reaction.

The first thought that entered my mind when I came home was how fearful I am that if it took me, his mother, that long to react, how long will it take if the reaction happens at school? Do educators know enough to be able to handle such a life threatening situation in a timely manner? Do the kids know enough to tell that something is not right with Ryan?

Parents have to rely on everyone around their child to manage his food allergy. That's a scary scenario. Even simplicities such as playing on a playground are concerns for those with food allergies. While there isn't always food present on the playground, the risk is still present. Imagine a child who ate peanut butter and jelly and got peanut butter on their hands. They have not washed their hands and then go out to the playground. When the child who now has peanut residue touches the playground equipment, my child now becomes at risk. Ryan can react simply by touching something that contains the food residue to which he's allergic. Food allergy awareness and education needs to encompass the many different ways a child can be exposed. Many parents, myself included, with children who have severe food allergies carry wipes around and clean areas where their children play. We walk around perceived as being overly-protective, or perhaps even crazy, paranoid parents—just to try and reduce risk wherever possible. We're NOT crazy. We're scared. Allergen protein can be as life threatening to my child as a gun in the hands of a toddler.

Each and every day Ryan is placed in scenarios beyond his or our control. Children like Ryan are vulnerable to allergic reactions not only at school cafeterias and restaurants, but in any public setting, from childhood parties to an afternoon spent at a friend's house. Ryan has been invited to a sleepover at a classmate's home. I could not allow him to attend, because of his food allergies. There's just not enough understanding by the general public as to how serious this is. Ryan recently attended a birthday party where kids were jumping on a trampoline. The birthday boy had a bag of Cheetos in his hand and decided to jump on the trampoline with them. Ryan immediately told the boy he couldn't be around him if the child was going to have Cheetos on his hand, as it could hurt him. Ryan proceeded to get off the trampoline and would not go back on. Seems like such a simple thing to most people. To me, that was a huge victory. I've educated Ryan enough that he is able to stand up for his own safety. I can only hope and pray that this will continue. As children grow up, they are going to test boundaries and push limits—a natural part of the maturation process. With the food allergic child, the teenage years can be particularly frightening as the kids struggle to fit in and “prove” their normalcy. One of my greatest fears is that my son will play down or try to hide his allergy from his peers out of a desire to not want to be “different.” If the people around him do not understand his allergies, they cannot help him in an emergency situation.

Efforts to protect our children in school, and other social settings are very important. However, what we need more than anything else is research to find a cure for life-threatening food allergies. Ryan participated in an exciting research study based at Duke University Medical Center in North Carolina. On each visit, Ryan was given small amounts of milk protein, exposing him to the very thing to which he is deathly allergic. The first visit caused an anaphylactic reaction that came on with rapid speed. The doctors and nurses were very well prepared, as they expected this type of reaction. I was asked by a friend who has a child with a peanut allergy how I could sit there and purposely cause my son to have that reaction. Well, my answer is simple. How could I not afford him the opportunity for a lifetime without the risk of this type of reaction occurring again? The hope was that, over time, he would build up a sort of immunity—they call it desensitization—and would be able to tolerate milk later in his life. Our participation in the Duke study is a good example of just how desperate parents of food allergic children are to find any kind of relief for our children. We drove 7½ hours each way to get to Duke because there are no facilities that we know of closer to home that are doing this kind of work. We stayed in town near Duke when we would have to make the visits and there was a constant danger that my son would have a severe, adverse reaction to the treatment. In fact, numerous times, Ryan had little mini reactions, like hives on his back or a few coughs. The doctors are, after all, feeding him something that could kill him.

Why are we willing to subject our son to this risk? Because he faces a greater risk every single day of his life simply by being surrounded by foods that can harm him. Research is our only hope for a long-term solution to these deadly allergies. There's no distance I wouldn't travel for the possibility of alleviating the daily risk Ryan faces. You know, the old saying “No Risk, No Reward” is how I feel about the research. There's never a guarantee that these research studies are going to “cure” my child. To not participate is almost guaranteeing the status quo—enrolling in the study offers hope. At the very least, we've contributed to the research. At best, we may have found a way to live without fear that our child could die from food.

You can help us. Millions of parents just like me are counting on the U.S. Congress to increase the amount of research that is conducted on life-threatening food allergies. There are only a handful of research centers like Duke around the country that are currently doing any kind of food allergy research. After 11 months of par-

ticipation in Duke's Research Study, Ryan is now able to tolerate milk. This is a huge victory for both Ryan and the study itself. Ryan can now come into contact with any milk protein and not have to reach for the EpiPen. The study has proven to work in his case. There is still much more research to be done. For example, we know that as long as Ryan has a daily dose of milk protein, he's ok. What we don't know is what happens if he goes without for days on end. This is where the research still needs to continue. We are a unique glimpse at what can be accomplished. The Federal Government currently spends under \$10 million a year funding research on food allergies. That is simply not enough. We need new research studies, more researchers and doctors investigating the disease, and funding to allow the best scientific minds in the field to find a cure.

Like any parent, I simply want my child to have the opportunity to grow and flourish in his life, and to reach his potential without limitations. On behalf of Ryan and the millions of other kids just like him, I am begging for your help.

Thank you!

Senator DODD. Excellent testimony. Thank you very, very much, Colene. We appropriate it.

Donna, nice to have you with us again.

STATEMENT OF DONNA KOSIOROWSKI, RN, MS, NCSN, SUPERVISOR SCHOOL HEALTH, WEST HAVEN SCHOOL DISTRICT, AND CONNECTICUT DIRECTOR, NATIONAL ASSOCIATION OF SCHOOL NURSES, WEST HAVEN, CONNECTICUT

Ms. KOSIOROWSKI. Thank you, Mr. Chairman, Mr. Alexander, and members of the subcommittee. It was my privilege to have you visit us in West Haven and it's my privilege to testify before you now. I'm also very honored to be here as a representative of the National Association of School Nurses.

I commend the subcommittee for bringing attention to the fact that more needs to be done regarding food allergy and anaphylactic management in schools. My testimony will explain that school nurses are indeed seeing more and more children with food allergies, and I'm also going to share some of my personal experience with the issue during my 23 years as a school nurse. I'd like to offer Connecticut's response to these life-threatening incidents in school as a model for other States.

School nursing today is very different than it was years ago. Even the last 10 years has seen drastic changes in school health. With inclusion, school nurses are now required to take care of every student and every health need.

School nurses definitely do report an increase among students with food allergies. Approximately 5 to 6 percent of the general pediatric population has an incidence of food allergy. However, children with food allergies can have good school attendance with a school nurse there to keep them healthy and safe while they're at school with us. I think you'll agree that healthy children learn better.

Therefore, school nurses are working toward ensuring that all school districts will have the opportunity to consider adopting Federal guidelines concerning the management of food allergies. Health needs and problems are not something that children leave at home. When they come to spend 6 or 8 hours a day in school with us, their health problems and needs come with them.

A recent law in Connecticut required the State Department of Education to develop guidelines for managing food allergies in our schools. The management plans allow for consistency when devel-

oping standardized and individualized health care plans for children throughout their school career.

With or without guidelines for food allergy management, schools are still obligated to maintain the health and safety of all students, including those with food allergies. Therefore it is necessary for the Secretary of Health and Human Services to consult with the Secretary of Education on the development of a voluntary policy for managing the risk of food allergy and anaphylaxis in schools.

In States like Connecticut we are very fortunate because we have a high ratio of school nurses to students. We have a plan of care developed and implemented by the school nurse. In a State like Tennessee, guidelines are on the books, but in 2007 Tennessee ranked 40th in the Nation for the school nurse-to-student ratio, which means that on average there's 1 nurse for 1,628 students. Who will be there in schools without nurses to implement the guidelines and ensure the safety of children needing rescue medication like epinephrine?

Having school-based food allergy management grants would greatly help local educational agencies throughout the country in need of creating and implementing the guidelines.

I'd like to spend the rest of the time I have sharing some reactions and how we make a difference in the lives of real school children when you prepare properly. Anaphylaxis has different symptoms in different people. Before there were guidelines, a girl with known food allergies—I call her "Sarah"—went to the nurse three times in the same day complaining about a stomach ache. On the third time that the nurse sent her back to class, Sarah never made it. She died of an anaphylactic reaction.

This tragedy was clearly a result of not having a standardized plan in place and a nurse who was not properly trained to recognize the symptoms related to anaphylaxis. Lack of training plus no guidelines is a recipe for disaster.

On a positive note, a family recently came to Connecticut from another State and wanted to register their little boy for kindergarten. The mother told the school nurse—and that school nurse was Sue, Senator Dodd—that her child, who I'll call "Danny," had severe food allergies and had been hospitalized several times for anaphylaxis. The mother claimed Danny had been denied entry to school in the other State because there was no plan in place for a child with his special needs.

The nurse was able to assure the mother that the Connecticut school district was ready and able to accommodate her child. Because of Connecticut's strong guidelines and proper training of nurses and school personnel, Danny has remained safe in school with us the entire time he's been in our district.

On behalf of the National Association of School Nurses, I urge this subcommittee to move legislation that will provide a voluntary policy for managing food allergy and anaphylaxis in schools and will establish school-based food allergy management grants. Food allergies are the ghost in the room. When they make their presence known, school nurses and school staff must be fully prepared to make sure no child succumbs to a preventable medical emergency.

Thank you.

[The prepared statement of Ms. Kosiorowski follows:]

PREPARED STATEMENT OF DONNA KOSIOROWSKI, RN, MS, NCSN

Mr. Chairman, Mr. Alexander, and members of the subcommittee, I am Donna Kosiorowski, a practicing School Nurse Supervisor from West Haven, CT School District, who is privileged to be here today representing the National Association of School Nurses (NASN) on the issue of addressing food allergies in schools. I commend the subcommittee for bringing attention to the fact that more needs to be done to prepare our Nation's schools to manage the risk of food allergy and anaphylaxis.

My testimony will explain that School Nurses are seeing increasing numbers of students with food allergies and the essential need to be prepared in the event a student has an anaphylactic reaction. I will also share with the members of the subcommittee personal experience with this issue over the course of my 23 years in school nursing and offer Connecticut's response to these life threatening incidents in school as a model for other States.

NASN's membership of over 13,000 School Nurses are performing duties today that go well beyond what school nursing was like 30-40 years ago when health care costs were affordable and children with chronic health conditions were not "mainstreamed." Even over the last 10 years, there have been rapid societal changes reflected in schools. Today, Federal laws like the Individuals with Disabilities Education Act (IDEA), result in children attending school in wheel chairs, on tube feedings, ventilators, central lines, pumps and other complex technologies. School Nurses are there to meet the needs of all students and the importance of managing life-threatening food allergies in the school setting is something that School Nurses are currently addressing. This life-threatening issue is recognized by NASN through the position statements we have included with our testimony and the informational resources we provide to our members.

School Nurses report an increase in the types of food allergies and other allergies in their school population. Approximately 5 to 6 percent of the general pediatric population have an incidence of food allergy, with eight foods (peanuts, shellfish, fish, tree nuts, eggs, milk, soy, and wheat) accounting for 90 percent of allergic reactions. However, children with food allergies can have good school attendance when a School Nurse is there to help them be healthy and safe at school. I think you will agree with the research that **Healthy Children Learn Better**. Knowing that healthy children learn better, School Nurses are working towards ensuring that all school districts will have the opportunity to consider adopting Federal guidelines concerning the management of food allergies. Health needs and problems are not something children can leave at home. When they come to school, their health needs and problems come with them. They spend 6-8 hours per day at school. Data clearly demonstrate that fatalities associated with anaphylaxis occur more often away from home and are associated with the absence or delayed use of epinephrine. The School Nurse is a reliable and trusted health care provider and parents feel comfortable consulting with the School Nurse. It is the School Nurse who is often the child's first and only access into the health care system. We provide frontline care and if society wants children "not to be left behind," then nurses need to be there to help them stay healthy and in school so they can achieve academic success.

Now let me share with you Connecticut's 2006 law requiring the State Department of Education to develop guidelines for managing food allergies in school, which includes Food Allergy Management Plans. The Management Plan is the basis for the development of guidelines implemented at the school level and provide for consistency across the State and in schools. The guidelines clearly outline prevention, education, awareness, communication and emergency response.

Consistency is important because all children must have standardized and appropriate individualized health care plans, developed through a formal process. This is protection for the children and families and consistency helps to prevent litigations. Plans should be based on medically accurate information and evidence-based practices using a process to identify, manage, and ensure continuity of care for students throughout their school career. Connecticut law allows School Nurses to train teachers, principals, coaches, and, in the case of epinephrine auto-injector, paraprofessionals, to administer medications to students with known allergies, not limited to food.

With or without guidelines for food allergy management, schools and school boards are obligated to maintain the health and protect the safety of any child with a health problem, including food allergies. Therefore, it is **necessary** for the U.S. Secretary of Health and Human Services to consult with the Secretary of Education on the development of a voluntary policy for managing the risk of food allergy and anaphylaxis in schools so that children are protected in a research-based and consistent manner. The Federal mandates of IDEA and Section 504 of the Rehabilita-

tion Act require schools that receive Federal funding to provide certain medical services. In fortunate States, like Connecticut, who have a high ratio of school nurses-to-students, a plan of care is prepared and implemented by the school nurse. In a State like Tennessee, there are guidelines on the books, but the school nurse-to-student ratio is ranked 40th in the Nation, which means that on average there is **1 nurse: 1,628 students**. Who will be there in those schools without nurses to implement the guidelines and ensure the safety of the children needing "rescue medication" like epinephrine? Having school-based food allergy management grants would greatly help local educational agencies throughout the country who are in need of **creating and implementing** guidelines, and hopefully as a result more school nurses will be placed in the schools to lead the effort.

Following are actual examples of how preparations for possible anaphylactic reactions make a difference in the lives of real school children.

Anaphylaxis has different symptoms in different people. Before Connecticut had their guidelines in place and they were implemented throughout the State, a girl with known food allergies, who I will call Sarah, came to the school nurse complaining of a stomach ache. Three times throughout the course of the day, the nurse sent her back to class. On her last trip back to the classroom, Sarah died from an anaphylactic reaction. This tragedy was clearly a result of not having a standard plan in place and a nurse who had not been properly trained to recognize all of the symptoms related to anaphylaxis. Lack of training plus no guidelines is a recipe for trouble.

On a positive note, when a family recently came to Connecticut from another State and wanted to register their little boy for kindergarten, the mother told the school nurse that her child, who I will call Danny, had severe food allergies and had been hospitalized several times for anaphylaxis. She further stated that the hospitalizations required intensive care and a tube to help him breathe. The mother claimed Danny had been denied entry to the school in the other State because there was no plan for "a child like him" and his health condition could not be managed safely in school. The previous school suggested consideration of home schooling. When coming to Connecticut, the mother was armed with information and knew the laws were on her side. The family was prepared to fight to get Danny into school with a plan to accommodate his special needs. Fortunately, the nurse was able to assure the mother that the Connecticut school district was ready and able to accommodate her child. Because Connecticut has strong guidelines, and nurses and other appropriate school staff have been trained for emergency situations, including established procedures with community EMS providers, Danny has remained safely in school.

Guidelines are a safeguard and protect both the child and the school district. Lack of guidelines can result in litigation and ultimately tragic deaths, as I described earlier. In Connecticut, I am aware of two court cases that were won by the school district because guidelines were implemented, individualized health care plans put in use, and staff training provided. Having a school district with every nurse trained to apply the same standard of care based on current guidelines is an ideal situation which has been honored by the courts. State guidelines give nurses a place to start and a process to follow which safeguards the student and the districts throughout the State. Although voluntary, the issuance of Federal guidelines would greatly help support students who move from one State to another.

On behalf of the National Association of School Nurses, I implore this subcommittee to move legislation that will provide a voluntary policy for managing the risk of food allergy and anaphylaxis in schools and will establish school-based food allergy management grants. With the growing number of students affected by food allergies, it is imperative that School Nurses have the support of the Federal and State governments for the development of individualized health care plans, emergency plans, and procedures for safe medication administration and storage. Food allergies can be like a ghost hiding in the room. When they make their presence known, School Nurses want to stand fully prepared to make sure each and every child does not succumb to a preventable medical emergency.

NATIONAL ASSOCIATION OF SCHOOL NURSES (NASN), POSITION STATEMENT—
THE ROLE OF SCHOOL NURSES IN ALLERGY ANAPHYLAXIS MANAGEMENT

HISTORY

Anaphylaxis can be deadly to children as well as adults. Among the general population, 1 to 2 percent are described as at risk for anaphylaxis from food and insects and a somewhat lower percentage are at risk from drugs and latex. Approximately

5 to 6 percent of the general pediatric population have an incidence of food allergy, with eight foods (peanuts, shellfish, fish, tree nuts, eggs, milk, soy, and wheat) accounting for 90 percent of allergic reactions. Food allergies are, in fact, the leading cause of anaphylaxis outside the hospital setting, accounting for an estimated 30,000 emergency room visits annually. It is estimated that 100 to 200 people die each year from food allergy-related reactions, and approximately 50 people die from insect sting reactions.

DESCRIPTION OF ISSUE

Care must be taken to differentiate between a true allergic response and an adverse reaction. True allergies result from an interaction between the allergen and the immune systems. Anaphylaxis is a potentially fatal reaction of multiple body systems. It can occur spontaneously. Data clearly demonstrate that fatalities associated with anaphylaxis occur more often away from home and are associated with the absence or delayed use of epinephrine.

RATIONALE

Education and planning are key to establishing and maintaining a safe school environment for all students. Those responsible for the care and well-being of children must be aware of the potential dangers of allergies. Prevention of allergy symptoms involves coordination and cooperation within the entire school team and should include parents, students, school nurses, and appropriate school personnel. Early recognition of symptoms and prompt interventions of appropriate therapy are vital to survival.

CONCLUSION

It is the position of the National Association of School Nurses that schools have a basic duty to care for students, utilizing appropriate resources and personnel. School nurses are uniquely prepared to develop and implement individualized health care plans within State nurse practice act parameters and to coordinate the team approach required to manage students with the potential for experiencing allergic reactions.

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NATIONAL ASSOCIATION OF SCHOOL NURSES (NASN), POSITION STATEMENT— EPINEPHRINE USE IN LIFE-THREATENING EMERGENCIES

SUMMARY

It is the position of the National Association of School Nurses that school nurses create and manage the implementation of emergency care plans for the treatment of life-threatening allergies in the school setting. State regulations, including nurse practice acts, will govern the need for protocols, standing orders, and/or individual orders for epinephrine administration.

HISTORY

An increasing number of school students and staff have diagnosed life-threatening allergies, an abnormal immunologic response. Exposure to the affecting allergen can trigger anaphylaxis, an overwhelming systemic response, characterized by drop in blood pressure, respiratory distress, loss of consciousness, and potential death. Anaphylaxis requires emergent medical intervention with an injection of epinephrine but does not eliminate the need to call Emergency Medical Services (EMS). Epinephrine injection will stop the allergic response by opening the bronchiole airway

passages for 10–20 minutes until more comprehensive emergency medical intervention can be obtained through the EMS system.

DESCRIPTION OF ISSUE

Avoidance of triggers, early recognition of symptoms, and immediate treatment are essential to the management of life-threatening allergies. There are both students and staff who have known life-threatening allergies, as well as those who have not been identified. Intervention with epinephrine is vital to saving lives.

Unfortunately, allergens of concern are readily encountered in the school environment and include food (5 percent children), insects (1 percent population), latex (1 percent population with increased incidence for those with spina bifida), medications, and exercise induced. Foods of primary concern are peanuts, tree nuts, fish, eggs, milk, wheat, and corn. Peanut allergy is rarely outgrown in adulthood. Allergy to cow's milk is more prevalent in children whereas shellfish allergy is more common in adults. Insects of concern are the species of Hymenoptera and include honeybees, wasps, yellow jackets, and hornets. Wasps and hornets are capable of stinging multiple times. Antibiotics are responsible for the majority of medication allergies and are less frequently present in the school setting (Mayo Clinic, Food Allergy).

RATIONALE

Medication and emergency policies in school districts must be developed with the safety of all students and staff in mind. Easy access to and correct use of epinephrine are necessary to avoid life-threatening complications.

The school nurse, parent, health care provider, and student should evaluate the self-managed administration of epinephrine by a student on a case-by-case basis. Written permission from the parent and health care provider must be obtained for students with known life-threatening allergies who will self-medicate or who will have epinephrine administered by a school district employee. The decision to allow a student to self-carry and self-administer epinephrine should take into consideration the age/developmental level of the student, the school nurse's assessment of the student's ability to self-medicate, the recommendations of the student's parent and health care provider, the need for a back-up supply, the specific school environment and the availability of a professional school nurse. The decision to delegate epinephrine administration to unlicensed assistive personnel is determined by State law and the professional nursing judgment of the school nurse (NASN, 2002).

An individual health care plan that includes periodic monitoring and nursing assessment, emergency plans, and evaluation should be written by the school nurse and maintained for every student with prescribed epinephrine. The school nurse should provide training for school staff in the recognition of life-threatening allergic reactions and the appropriate first aid/emergency measures that should be taken as determined by district policy and State law.

School districts must establish direction for handling episodes of anaphylaxis in students and staff with no previous history of life-threatening allergies. State laws governing nursing practice will determine the need for protocols, policies and procedures in the management of injectable epinephrine in the school setting.

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Senator DODD. Thank you, Donna, very, very much. I appreciate your good work over the years, too; very proud of you——

Ms. KOSIOROWSKI. Thank you very much.

Senator DODD [continuing]. And the work you've done.

Doctor, I'm glad to hear you again, for a second time. I heard you yesterday and you were terrific, and glad you're here today as well.

STATEMENT OF HUGH A. SAMPSON, M.D., PROFESSOR OF PEDIATRICS, MOUNT SINAI SCHOOL OF MEDICINE, AND PRESIDENT, AMERICAN ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY, NEW YORK, NY

Dr. SAMPSON. Thank you, Senator. Mr. Chairman, Ranking Member Mr. Alexander, and members of the subcommittee, I'm very pleased to be here today to participate in this important hearing on the challenges confronting food allergic children and their families.

I have spent over 25 years conducting research and caring for children with food allergic disorders. I would like to thank you, Senator Dodd, for holding this important hearing during Food Allergy Awareness Week. Families across America are working this week to educate their communities about food allergies and it is inspiring to them to see your support.

I am also grateful for your leadership as sponsor of S.1232, the Food Allergy and Anaphylaxis Management Act, and your support for Federal policies to protect food allergic children.

While I know you are well aware of the impact of food allergies, Senator Dodd, I would like to provide some general information for the benefit of committee members. A food allergy occurs when a person's immune system attacks harmless proteins in our food. The immune system is the part of the body that usually fights infections and other harmful organisms. In this case the responses are misdirected. The food is misidentified as the body's enemy and the immune system attacks the food as it would a parasite or an infection. Foods most commonly responsible for allergic reactions are milk, egg, peanut, tree nuts, fish, and shellfish.

While most children outgrow milk and egg allergies; peanut, tree nuts, fish and shellfish allergies are usually lifelong. More than 10 million Americans have food allergy, including almost 3 million children, and the prevalence of food allergies and associated anaphylaxis is increasing. In a national survey, we found that the rates of peanut allergy doubled in children less than 5 years of age from 1997 to 2002. Similar findings have been reported in the United Kingdom and other industrialized countries.

Through research, we are trying to identify the cause of this dramatic increase. There are several theories under investigation, as Dr. Fauci mentioned, including the hygienic hypothesis, which

states that children in our culture are exposed to fewer germs; the lack of exposure seems to affect the normal programming of the immune system, thereby making it less effective at distinguishing harmful pathogens from harmless food.

Another theory suggests that children who have compromised skin barriers, such as children with atopic dermatitis or eczema, are sensitized to food through contact with food proteins in body creams or residual food on the hands of their parents, caregivers, or siblings. The majority of young children with food allergies and atopic dermatitis develop respiratory allergies and asthma, something called the allergic march. These children are at greatest risk for severe and occasionally fatal anaphylactic reactions.

The impact of food allergies in the real world of children and families is far more difficult to describe. Food is at the center of almost all our social activities and therefore the potential threat is everywhere. As I found with my daughter who is allergic to egg and now walnuts, parents must spend hours in grocery stores scrutinizing labels and phoning companies to get clarification on ingredient labels. They also live every day knowing their child can walk out the door to day care or school or church or to camp and end that day in the emergency room or worse.

Data from an FDA survey published this January suggests that there are at least 125,000 emergency room visits each year for food allergy, that about 15,000 of these are for anaphylactic reactions, with over 3,000 ending in hospitalizations. Other surveys suggest even higher numbers of anaphylaxis cases and provide estimates of 100 to 150 deaths due to food allergy each year.

So what can be done? I would strongly support the five steps forward for food allergy initiative announced yesterday by the Food Allergy and Anaphylaxis Network (FAAN), which was endorsed by the American Academy of Allergy, Asthma, and Immunology and over 64 organizations from across the country. These five steps include: passage of S. 1232, the Food Allergy and Anaphylaxis Management Act; development of national guidelines for the diagnosis and management of food allergy for health care professionals; significantly increased funding for research in food allergy and anaphylaxis; expand efforts by the U.S. Food and Drug Administration to improve food allergen labeling; and creation of a national clearinghouse at the Center for Disease Control and Prevention and food allergy for the general public as well as health care professionals.

If these recommended policy initiatives are implemented, we will reduce the incidence of fatal food allergic reactions in our country.

I would like to focus on the need for expanded research. Dr. Fauci and the NIAID are to be commended for their recent initiatives in the area of food allergy. In my 25 years in food allergy research, I have seen the field move from just trying to understand the manifestations of food allergy to the point where new therapeutic strategies are at hand, some now starting in human trials. However, I can tell you with absolute certainty that unless Congress provides NIH with significant funding increases for research on food allergy and anaphylaxis we will not make progress toward the potential breakthroughs.

I agree with FAAN, which is recommending annual increases of \$10 million each year for the next 5 years to pursue the goals of the expert panels Dr. Fauci mentioned and carry out promising clinical trials under way. I strongly encourage this subcommittee to formally recognize this need and encourage the Appropriations Committee to provide this additional support.

It is important to recognize the size of this problem—over 10 million Americans and their families affected—and that most of the research necessary to improve methods for preventing and treating food allergy simply is not being done.

Once again, I would like to thank you, Senator Dodd and the subcommittee, for convening this important hearing. Thank you.

[The prepared statement of Dr. Sampson follows:]

PREPARED STATEMENT OF HUGH A. SAMPSON, M.D.

My name is Hugh Sampson, and I am pleased to be here today to participate in this important hearing on the challenges confronting food-allergic children and their families. I am the Chief of the Pediatric Allergy and Immunology Division and the Director of the Jaffe Food Allergy Institute at the Mount Sinai School of Medicine in New York. I have spent over 25 years conducting research and caring for children with food allergic disorders. I am also president of the American Academy of Allergy, Asthma, and Immunology (AAAAI), an international organization of over 6,500 allergist/immunologists, allied health professionals, and others with a special interest in the research and treatment of allergic diseases.

I would like to begin by thanking you, Senator Dodd, for holding this important hearing during *Food Allergy Awareness Week*. Families across America will be working this week to educate their communities about food allergies, and it is inspiring for them to know that you are doing the same here in the U.S. Senate. In addition, I am grateful for your leadership as the sponsor of S.1232, the *Food Allergy and Anaphylaxis Management Act*, and for your support for Federal policies to protect food allergic-children. Passage of your legislation is critically important to the ability of schools and parents to assure the safety of children with food allergies.

In addition, I am pleased to have the opportunity to express the strong support of the AAAAI for the “*Five Steps Forward for Food Allergy*” initiative announced just yesterday by the Food Allergy and Anaphylaxis Network (FAAN), a national organization dedicated to raising public awareness of food allergies through education and advocacy. I serve as Medical Director of FAAN, and believe that if the five recommended policy initiatives are implemented, we *will* reduce the incidence of fatal food allergic reactions in our country.

BACKGROUND ON FOOD ALLERGY

While I know you are well aware of the impact of food allergies, Senator Dodd, I would like to provide some general information for the benefit of the committee members. A food allergy occurs when a person’s immune system “attacks” harmless proteins in our food. The immune system is the part of the body that usually fights infections and other harmful substances, but in this case the responses are misdirected. A food is misidentified as the body’s enemy, and the immune system “fights” the food as it would a parasite or infection.

In children, the most common foods causing significant reactions are milk, egg, peanuts, tree nuts, fish, shellfish, soy and wheat, while in adults the most common foods are shellfish, peanuts, tree nuts and fish. Most children outgrow their allergies to many foods, but not typically to peanuts, nuts, fish, and shellfish, which are often considered life-long allergies.

In the majority of food allergic reactions, the symptoms will begin within minutes after an exposure, although a delay of up to an hour or more is possible. Some reactions can be mild including itchy skin and rashes, itchy mouth, and stomach aches. The more severe and life-threatening anaphylactic reactions can include swelling, hives, welts or itchiness of the skin; digestive symptoms such as severe stomach pain, nausea, vomiting, and diarrhea; respiratory symptoms such as hoarseness, difficulty swallowing, trouble breathing, wheezing, repetitive coughing, and in the worst cases, throat closing; and reduced blood circulation resulting in paleness, dizziness, passing out, low blood pressure, and even loss of pulse. Sometimes a reaction will subside and then start up again 1 to 3 hours later. There are also a number

of gastrointestinal allergies that come on more slowly but can lead to abdominal pain and nausea, weight loss and failure to thrive.

There is no cure for food allergy. Strict avoidance of the allergy-causing food is the only way to avoid a reaction, but even trace amounts of a food allergen invisible to the naked eye, such as residual food on dishes and utensils simply wiped clean, can cause a severe reaction. In some cases the food does not even have to be swallowed. Inhaled food proteins vaporized during cooking have caused severe and even fatal reactions in some individuals. Prompt administration of epinephrine, also called "adrenaline," is the best method we now have for controlling a severe reaction. It is available by prescription as a self-injectable device.

More than 10 million Americans have food allergies, including almost 3 million children. The prevalence is highest in young children, with 6–8 percent of children under 4 years of age affected by food allergies. The prevalence of food allergies and associated anaphylaxis is increasing. For example, in a national survey, we found that the rates of peanut allergy doubled in children less than 5 years of age from 1997 to 2002, and similar findings were reported in the U.K. Globally, food allergies are most prevalent in industrialized countries like ours with similar lifestyles and eating habits. Through research, we are trying to identify the causes of this dramatic increase. There are several theories under investigation including the question of whether children in our culture are exposed to fewer germs, thereby requiring the immune system to be less active in fighting germs and somehow making it less effective at identifying certain foods as harmless. The onset of food allergy is often preceded by atopic dermatitis, commonly known as eczema, in which the normal skin barrier is defective. Another theory suggests that contact with creams containing food proteins or residual food on the hands of parents, caregivers and siblings may sensitize these children to the food. Other theories include the rise in consumption of omega-6-containing foods and decreased consumption of omega-3 polyunsaturated fatty acid-containing foods, reduced dietary antioxidants, and excess or deficiency of vitamin D. The majority of young children with food allergies and atopic dermatitis go on to develop respiratory allergies and asthma, something allergists call the "allergic march." In addition, children with food allergies and asthma are more likely to suffer from severe asthma, and are at greatest risk for severe and occasionally fatal anaphylactic reactions. We believe that a better understanding of the inter-relationship of these diseases is critical to developing new methods to prevent and treat food allergies.

This gives you some idea of the challenges that food allergies present to health care professionals. The impact in the real world of children and families is far more difficult to describe. Food is at the center of almost all of our social functions, and therefore presents a potential threat to the food allergic individual everywhere he or she turns. As I found with my second daughter, who has allergy to walnuts, parents must spend hours in grocery stores scrutinizing labels and phoning companies to get clarification on ingredient labels. In addition, many parents of a child with food allergies live every day knowing their child can walk out the door to day care, or school, or church, or camp, or literally any place in which food is served and end that day in the emergency room, in the hospital, or in an intensive care unit on a ventilator, or rarely, even dead. Data from an FDA survey published in January of this year, utilizing the National Electronic Injury Surveillance System of selected emergency departments around the United States, suggest that there are about 125,000 emergency room visits each year for food allergy, and that about 15,000 of these are for anaphylactic reactions, with over 3,000 ending in hospitalizations. Somewhat alarming was the fact that only 43 percent of the anaphylactic cases were accurately diagnosed by the emergency room staff, a finding frequently reported in similar surveys, emphasizing the need for better health education training and guidelines for health care professionals. Other surveys suggest even higher numbers of anaphylaxis cases, and while accurate data is very difficult to come by, it is estimated that anaphylaxis caused by food allergy results in 100–150 deaths each year in our country. Death can be sudden, sometimes occurring within minutes. You can imagine how the life of an entire family is completely disrupted as they strive to avoid this fate. Far worse, imagine seeing your daughter die in a shopping mall while you are out looking for her prom dress, or your young son go into shock and eventually die from tasting some of a peanut snack unbeknownst to you while you are watching the Super Bowl together, or learning that your son died on a camp canoe trip from an anaphylactic reaction due to residual peanut butter on a knife used to make his sandwich.

RECOMMENDATIONS

As I noted earlier, the American Academy of Allergy, Asthma & Immunology and I, personally, strongly support the “*Five Steps Forward for Food Allergy*” advocacy initiative announced yesterday by FAAN with the endorsement of nearly 70 organizations from across the country. These five steps include:

1. Passage of S. 1232, the Food Allergy and Anaphylaxis Management Act, to help schools create guidelines for managing food-allergic children;
2. Creation of a national clearinghouse at the Centers for Disease Control and Prevention on food allergy for the general public as well as health care professionals;
3. Development of national guidelines for the diagnosis and management of food allergy for health care professionals;
4. Significantly increased funding for research on food allergy and anaphylaxis; and
5. Expanded efforts by the U.S. Food and Drug Administration to improve food allergen labeling.

I would like to focus specific attention on the need for expanded research. In recent years, experts have been convened to identify the most promising avenues of research on food allergy and anaphylaxis:

- In March 2006, the NIH Expert Panel on Food Allergy, convened by the National Institute of Allergy and Infectious Disease (NIAID), released a report detailing an agenda of research questions that should be pursued if we are to succeed in identifying vaccines or improved treatments for food allergy. The report recommended additional basic and pre-clinical research on specific questions; clinical trials to evaluate promising new approaches to the prevention and treatment of food allergies; and expanded studies of the epidemiology and genetics of food allergy. The report also recommended that efforts be undertaken by the NIH and the FDA to resolve impediments to the design and conduct of clinical trials for the prevention and treatment of food allergy. Unfortunately, due to grossly inadequate funding, most of the research recommended in this report has not been pursued.

- In February 2006, the Journal of Allergy and Clinical Immunology published the report of a symposium on anaphylaxis convened by the NIAID, the Academy, FAAN and others. This report detailed an agenda of research questions to be pursued to enable us to better understand anaphylaxis and improve methods for prevention and treatment. Again, due to grossly inadequate funding, most of these research initiatives have not been pursued.

Dr. Fauci is to be commended for the initiatives the NIAID has undertaken in the area of food allergy. I have been fortunate to be funded by the NIH for the past 25 years to support my research in food allergy. In that period of time, the field has moved from just trying to understand the manifestations of food allergy to the development of new diagnostic and treatment modalities, several of which are now just starting in clinical trials. However, I can tell you with absolute certainty that unless the Congress provides NIH with significant funding increases for research on food allergy and anaphylaxis, we will NOT make progress toward break-throughs in the prevention and treatment of food allergies. In addition, an investment must be made in the training of researchers in the field of allergy to pursue a significantly expanded research agenda in the areas of food allergy and anaphylaxis. FAAN is recommending annual increases of \$10 million per year for 5 years (an additional \$50 million over 5 years) to bring the budget for research on food allergy and anaphylaxis to a level that will allow us to pursue the research recommended in the two reports I have cited and to support the promising clinical trials underway. I strongly encourage this committee to formally recognize this need and encourage the Appropriations Committee to provide this additional support at a minimum. I understand that the Federal budget is extremely tight at this time. However, it is important to recognize the size of this problem, over 10 million Americans and their families affected, and that most of the research necessary to improve methods of preventing and treating food allergy simply is not being done.

CONCLUSION

Once again, I would like to thank you, Senator Dodd, for convening this important hearing. The American Academy of Allergy, Asthma and Immunology looks forward to working with you to achieve the enactment of S. 1232. In addition, we hope you and all members of this committee will support the initiatives included in FAAN’s “*Five Steps Forward for Food Allergy*” statement and that you will take steps to address the totally inadequate funding for research on food allergy.

Thank you for the opportunity to participate in this hearing. I would be happy to answer any questions.

Senator DODD. Well, thank you very, very much, all of you. Very, very helpful testimony, and I'm very grateful to you for your sharing with us your personal stories as well as the work, doctor, you're doing in this field.

Let me begin, if I can, with you Teresa and with Colene. What advice or comments might you have for other parents, whose children have food allergies and those who don't, about being prepared. You've been through this, obviously. I think sometimes, with all due respect to Senators and doctors, people listen to other parents. Are there any thoughts you want to share, advice you can give parents?

Ms. WALTERS. I think my biggest piece of advice for other parents would be, don't let other people tell you how to react to your child's food allergies. Don't let them tell you that you're being over-protective.

Senator DODD. We have a story I told, I think I told Lamar this story. One of the problems we've had, we fly a lot, obviously, going back and forth to Connecticut a lot. Without naming any particular airlines, the difficulty sometimes of getting them to understand that peanuts—calling ahead of time, stopping at the gate before you get in, getting on the plane. Invariably, the flight attendants have not been told by anybody. So they look at you with annoyance.

We actually had a flight one time where the flight attendant told us we had to get off the plane, because every other flight they served peanuts on. We were in Phoenix, AZ, on our way back home to Connecticut, a long day with a 2-year-old—less than a 2-year-old; with a 1-year-old—and they said we had to get off the plane because that was the choice.

Needless to say, we stayed on the plane and there were no peanuts served. Nevertheless, it took me battling to do it. I shouldn't have to battle for this.

We had a woman behind us one day eating something with peanut butter, and I said, I apologized and explained that my daughter had a severe allergy and could have a potentially serious reaction to peanut butter. Her comment was: "What, is she going to break out in a little rash?" I almost felt like saying, well, maybe I shouldn't bother in a sense, with that reaction, letting other people sort of cause you to be less than vigilant. It's a good piece of advice.

Colene.

Ms. BIRCHFIELD. I would echo her sentiment. As a parent, I think that the key piece is to trust yourself and only yourself, and educate yourself as much as you can, try to educate everybody around you. You may ruffle some feathers along the way, but it's necessary. You must be the advocate for your child.

Senator DODD. Do you have any—do either of you have a history in your family of food allergies?

Ms. BIRCHFIELD. None in my family or my husband's.

Senator DODD. How about you?

Ms. WALTERS. I have very minor food allergies. I'm the only person in my family who does, though.

Senator DODD. But nothing as serious as you had in the case here?

Ms. WALTERS. No.

Senator DODD. Getting people educated about EpiPen and Twinject—we did it the other day in Connecticut. It was very good. The woman I was sitting next to, Donna, actually got up—I don't know if they covered it that night on television; I didn't watch the news. She actually went through a whole demonstration for our local TV station on how to use an EpiPen. I thought it was pretty good. They seemed to be interested as well in how it worked.

Any thoughts you'd have as parents or Donna on how we can do a better job of educating the use with EpiPen, the importance of it?

Ms. KOSIOROWSKI. Fox News actually did a good job, and they had Chris on.

I think that it's repetition, it's reinforcement. You can't teach it once and expect that people are going to remember. You have to teach. For the school nurses, we teach the school staff. For the parents, because our nurse is also a parent of a child, you have to educate their friends, their friends' families, anyplace they go. I think you just have to practice and repeat and just be vigilant. You can never let your guard down.

Senator DODD. Tell me, if you could, Donna, about the Good Samaritan laws, because we run into it all the time, you'll have people in various States say: "Look, just the liability; the insurance is too much"; we refuse to administer this kind of—applying the EpiPen. I mean, they just don't do it. We've heard this in a number of places.

Are you familiar with this, what I'm talking about?

Ms. KOSIOROWSKI. Yes.

Senator DODD. What are some States doing? Are there States or localities that are handling this better than others?

Ms. KOSIOROWSKI. I can't answer that except for Connecticut. Health care providers are obviously covered under the requirements of their license and I'm covered under the Nurse Practice Act. The Good Samaritan law actually applies to teachers, principals, people that respond with good intent, so that they won't be held liable for harm if they mean to do well. That's a concern that our teachers and our staff certainly have as far as liability. We tell them, if you're trained, if you do the right thing with the right intentions, then you'll be OK and that law will cover you.

Senator DODD. In the absence of that, you can understand why there's a reluctance because of the fear of litigation that goes on in certain areas.

Ms. KOSIOROWSKI. I think—again, I can only address Connecticut. I included in my testimony, there were two cases in Connecticut where the courts found actually in favor of the school districts because they had guidelines in place, they had a standard of care that was shared throughout the district, and we also share the same standard of care throughout the State, so that we do have a guideline in place.

I think you're more liable without guidelines than you are with them.

Senator DODD. Is that a Connecticut case?

Ms. KOSIOROWSKI. Yes, it was. There were two.

Senator DODD. And they held for the school district?

Ms. KOSIOROWSKI. Yes, that we did everything we could, we did it right, we weren't discriminating against any one child because we had the same guidelines, with individual plans for each child.

Senator DODD. Dr. Sampson, again thank you immensely for your work. I asked Dr. Fauci some of the questions and I would be curious as to your response as well, to some of these questions regarding the increase, what appears to be a dramatic increase. Clearly some of it is better detection and people getting diagnosed. Give us your appraisal of all of this, where things are, what direction we're heading in, and whether or not we're looking at just better detection, or is there a real rapid increase in food allergies?

Dr. SAMPSON. Based on the studies we did, I would say without question there's an increase going on, that when we did the national survey looking at the prevalence of peanut allergy we used the exact same methods so that we would be sure there was no change in the way we tried to gather the questions that might influence people to answer in a different way. We're very confident in those figures, that there was a doubling of peanut allergy in that 5-year period. We are just about to do a third survey now, another 5 years on, to look at it.

As I said, we know from other countries, such as the United Kingdom, where they are reporting exactly the same thing. I'm sure that there is more awareness. I know when I talk to people about food allergy now compared to when I started doing this, people are more aware of it. I think, as Dr. Fauci pointed out, it's not hard to miss anaphylaxis. You can't be having it in the past and not know it was there. I think there's no question that it's increasing.

As he also pointed out, and I'm sure you want to know and we want to know, is why is that happening? There are lots of theories out there. We need more people looking into it. We need more research trying to address it. I think one of the things we can take away is when we look at the countries that are affected, it's countries like ours. It's the way we prepare food. It's the way—our customs in eating, our customs in introducing children to foods that are having the problem.

You can go to the Scandinavian countries, which have a very similar lifestyle as we do, but they introduce foods in a different way, and you're not seeing peanut allergy at the same rate that we see it here. We need to look into these things. We need to look at how the foods are prepared, as Dr. Fauci brought up, with the idea of the dry roasting of the peanut that we do primarily here, as compared to boiling.

One of the things I point out to people, we developed a mouse model of peanut anaphylaxis and in order to sensitize that mouse to be able to anaphylax we have to use dry roasted peanuts. It will not work if we feed it boiled peanuts.

There are things about the structure of these proteins, the processing, that we need to know more about.

Senator DODD. That's phenomenal. I remember you talking about that yesterday, just the preparation and how it works.

Can you talk more about what studies have shown with regard to the early exposure to the allergens? I was thinking as you were just commenting on the last question of something that people I remember telling Jackie and me some time ago, that in the first 3 months after a child has arrived that you ought to keep them away from all of these, these foods, because just the maturation of the—

Mrs. DODD. Years.

Senator DODD. Years. What did I say, months?

Mrs. DODD. Months.

Senator DODD. I meant years. Thank you, Jackie. That's the reason you're here.

Dr. SAMPSON. I was going to say, I think the thing that we realize now—the American Academy of Pediatrics just came out with new recommendations—is that the results of the studies are conflicting. We're not really sure what is the best direction. As Dr. Fauci pointed out, initially we thought the best thing to do was to completely avoid the particular food for a period of time, until the immune system was mature and we thought would be able to handle it more effectively.

One of the things that we have found out is it's almost impossible, with the way we prepare foods in this country, to completely avoid milk, completely avoid egg, completely avoid peanut, and those low-level exposures may be more of a problem than just feeding it to somebody. We have some studies that do suggest that if you could, in fact, totally prevent exposure you may be OK, but that's really not something that's possible.

We have to look at a new paradigm which was brought up, that maybe we need early exposure of higher amounts to force the immune system to become more tolerant. This is something that has to be looked into.

Senator DODD. You mentioned the \$10 million a year for 5 years. Senator Alexander raised the issue earlier, Dr. Fauci talked about I think, what did he say, doubling the amount was his number. It was something like \$26 million. Flesh out that number for me a bit. Why the magic number? What is it about your number?

Dr. SAMPSON. My number that's better? One of the things I'm looking at is we have a consortium on food allergy research that's funded by the NIH and we are conducting studies such as desensitization to egg, sublingual immunotherapy to peanut. We have various studies. We have five centers involved in this, Duke being one, Arkansas, Hopkins, Denver, and Yale. We are really underfunded for what we're trying to do.

If we had more funding, we would be able to bring more centers, which would allow us to move it forward more quickly and would also give us the personnel to be able to do these studies. Right now I'm aware of five different ways that we can try to treat food allergy that have been looked at in various model systems and I think it behooves us to look at these as quickly as possible. If one of those works we are way ahead of where we are now.

Senator DODD. Would you share with us—I heard you yesterday, but would you share with Senator Alexander and the committee?

Dr. SAMPSON. One of the ones that was brought up is this oral immunotherapy. This is something that really was started back in the early 1900s, but they didn't understand it and there were prob-

lems. Now it's being looked at in a very careful way and we're trying to understand some of the basic immunology that is brought about by doing this.

There's another form where we're trying to add an anti-IGE antibody, something called Zoler, which causes the immune system to process these proteins in a different way and may be actually able to prevent a lot of the side effects we see with oral immunotherapy, but also make the body become tolerant more quickly.

There is another called sublingual immunotherapy, with special cells in the floor of the mouth that process food proteins and take them to an area that's more likely to bring on this regulatory effect that Dr. Fauci had mentioned earlier.

We also have a recombinant protein vaccine that we've developed, and this is one we've been working on with the group at Yale, where we can basically turn off the immune response, at least in our animal model. This is something that we're hoping to bring into clinical trials as quickly as possible.

Now, I have a colleague of mine that came with me to New York from Hopkins who was very interested in herbal preparations, and she has actually developed this preparation that totally blocks anaphylaxis in the food allergic animal model. This is something that we are just starting human trials with. We have an IND from the FDA to do it, but again we're the only place doing it. So you can imagine it's not moving along at a very fast rate.

If we had something like 5 centers involved, 10 centers involved, this kind of research could be looked at much more quickly.

Senator DODD. The herbal one is one out of China, is that correct?

Dr. SAMPSON. She actually developed this—she trained in China. Interestingly, there's nothing in ancient Chinese medical literature about food allergy. Knowing about other disorders, she came up with this initial formulation that we've slightly modified. I have to tell you, when we started I was very skeptical and made her do it over and over and over again. It's very effective and I have to admit that there is no evidence that any of the particular herbs in this formulation cause any serious side effects. They have all been used for centuries, and to me it seems like a very low-risk way. If it happens to work, it will be a phenomenal protection for people with any kind of food allergy leading to anaphylaxis.

Senator DODD. Very exciting.

Lamar.

Senator ALEXANDER. Well, that is extraordinarily interesting.

May I ask you about labeling, Dr. Sampson. A young friend of mine, a mother who has been living in London the last couple of years, has said to me a couple of times that labeling in England is better than labeling here. Can you talk to me about that? Are there things we should be doing that would improve labeling here, that would be helpful to parents or others?

Dr. SAMPSON. I think the intent of the Food Allergy Protection Act that Senator Dodd brought up earlier is a great idea. Having had to stand in these stores and try to figure out what sodium caseinate or potassium caseinate or whey is, when all it means is milk—for me, I'm used to seeing those names. That has been a tremendous improvement.

The thing that has sort of an unexpected side effect of that is when companies are very fearful of possible contamination, and if they don't list a particular food, say peanut, they know that in rare occasions if you make a product on the same line that had processed something that had peanut in it, that there's a possibility of contamination.

We're now starting to get all these labels that say "May contain peanut," "Made in a plant that contained peanut." I think there are about 40 different variations that can be there. We need to have the confidence in the label when it says or it doesn't say peanut, that we know that it's safe. All these variations are making especially my teenage population that I see start to ignore them. We know that some of those are going to contain peanut protein in it.

Senator ALEXANDER. Is it true that Europe and/or London has a different labeling system?

Dr. SAMPSON. The main difference I think is that they don't have all these variations on the label. Now, that's not to say that that is necessarily better, but it's certainly easier for the patient.

Senator ALEXANDER. Do any of the other witnesses have a comment on labeling?

Ms. BIRCHFIELD. Well, I agree with what Dr. Sampson said. It's just, as a parent the way the labeling has now come, where you have in big bold letters "Contains milk, egg, or peanut." Sometimes mistakes are made. I don't trust the labeling system still. I still rely on reading the sodium caseinate and every individual ingredient because I feel like if I don't I'm still putting my child at risk.

I think part of the problem with the labeling, too, is that once you have it down you have to read it again because the labeling keeps changing, the ingredients keep changing. You can't assume the same product you ate last week will be what you're eating today.

Dr. SAMPSON. We've actually had situations where in one part of the country it contains the milk protein, in another part of the country it doesn't. Patients just have to be constantly vigilant.

Senator ALEXANDER. Ms. Birchfield, in your experience with the Tennessee law do you see things that need to be improved in that?

Ms. BIRCHFIELD. Well, I wanted to just add something to what the doctor just said about one part of the State being different than the other. Going back to the school setting, a good example is when I went in to read ingredients for chicken patties that the Tennessee schools serve at Attison Elementary where my child attends, Ryan can eat that brand—it's Tyson chicken patties—when I buy them at the grocery store. However, he cannot eat them when the school serves them, because the distribution center from which they get their patties puts an egg—puts egg in those chicken patties, whereas the distribution centers that make the ones that go to the grocery stores do not contain egg.

It just becomes a big challenge when you're trying to figure out what's safe and what's not.

Senator ALEXANDER. The comment was made that there's one nurse for every 1,600 children in Tennessee. Does that mean there needs to be a school nurse in every school?

Ms. KOSIOROWSKI. I wouldn't sit here and make that recommendation. I think you have to look at the acuity of the stu-

dents. My reason for quoting the statistic was because in Connecticut one of the reasons why we feel we're fairly successful is we do have a good nurse-to-student ratio, in that we have about one nurse for 504 students. That I think you have to look realistically at what a nurse can safely manage in terms of keeping the kids safe.

Senator ALEXANDER. If there is no school nurse, can the staff—can teachers be trained to deal with this?

Ms. KOSIOROWSKI. Every State has different laws in terms of what can be delegated and what cannot. In Connecticut we can train principals and teachers to administer medication, but you do have to make sure that there's a nurse, if not on site, available for supervision, consultation, and you have to make sure that she's there to do the initial training and then to reinforce her training throughout the school year, or his, because we do have male school nurses too.

Senator ALEXANDER. Maybe it was Ms. Walters who mentioned, or someone mentioned, that the medicine was locked in the office of the—

Ms. BIRCHFIELD. That was me. Now, Tennessee, as you know, does have the Management Act for the guidelines for the management of food allergies. All of the staff at our school, they are trained with how to use the EpiPen. That trickles down from the principal all the way to the custodial workers. Everybody knows how to use one.

The issue that I have is how they get it, because if it's locked up it's hard for them to get to the medication. The training doesn't help if they can't get to the medication.

Senator ALEXANDER. Where should it be in your opinion?

Ms. BIRCHFIELD. Now, the principal at our school is very gracious and willing to work with me. In addition to having Ryan's medication locked up in the nurse's office—coincidentally, our nurse is only in the building 2 days a week. It's locked in the nurse's office, but she also allowed for my son to carry his medication with him. So his teacher created a little system, a bag that she keeps, and it travels with him to the playground, to gym, to music. Everywhere Ryan goes, his medication goes with him.

Senator ALEXANDER. Is Ryan the only child in the school in Oolteway with a food allergy?

Ms. BIRCHFIELD. There's one other child who has a peanut allergy, and I'm not currently aware what he does with his medication.

Senator ALEXANDER. You mentioned the Good Samaritan laws and the effect, the beneficial effect, that they would have in encouraging staff members to take the actions they should take. Would there be any risk that a model set of guidelines would make schools feel they'd need to automatically adopt it, otherwise there would be liability for not adopting it?

Ms. KOSIOROWSKI. Again, I could only talk about Connecticut. Our guidelines do include the Good Samaritan Act. I think you have to make people feel comfortable, you have to make your staff feel comfortable, that they're going to be protected, because liability is a concern for them.

I'm not sure whether the Good Samaritan Act would apply in other States. In Connecticut we do include that.

I would like to share some information in regard to the locking of the EpiPens if I may.

Senator ALEXANDER. Certainly.

Ms. KOSIOROWSKI. In Connecticut we develop our care plans based on individual needs and the abilities of the child. We do allow some children to carry their EpiPen with them. Age has very little to do with it. It's the ability of the child to understand the process when they use the EpiPen. We've also worked out plans where teachers would carry the pen with them and would pass it from teacher to teacher.

There are a lot of different ways. We try very hard not to lock the epinephrine up because we want it where the child is.

Senator ALEXANDER. Well, Senator Dodd, this has been very helpful to me and I'm sure to anyone watching. I want, Ms. Walters, to especially thank you for coming and telling your story. To all of you, this has been a big help to me, and I thank Chris for his leadership.

Senator DODD. Thanks very much.

You know, I can't resist. First of all, just a question. There is the concern, well, is there some danger in using an EpiPen? Is there some sort of a medical reaction? I know the answer to that, but, doctor, would you or Donna, either one of you respond?

Dr. SAMPSON. I think if people are shown how to use it, I'm not aware of anybody who's ever had a serious reaction following the use of an EpiPen. It's a relatively safe drug used the way it's administered by the EpiPen. Especially in children, the risk is very negligible.

Senator DODD. Donna, why don't you stand up. You brought an EpiPen with you.

Ms. KOSIOROWSKI. I did.

Senator DODD. This is being shown on CSPAN. Can you show us how it works?

Ms. KOSIOROWSKI. Sure. I just want to say, we have a well known allergist in Connecticut, Dr. Rosen, who you may be familiar with. He said you're not going to hurt anybody by giving them epinephrine, but you could kill them by not giving it.

Senator DODD. That's right.

Ms. KOSIOROWSKI. Senator Alexander, if I may, I'm not making a recommendation, but I will say I think every child deserves a school nurse.

[Laughter.]

Senator DODD. I would have been shocked to hear otherwise.

Now show us how it works.

Ms. KOSIOROWSKI. In order to be fair, epinephrine—EpiPens are a brand name. We also have something called a "Twinject." It's very simple to use. These are trainers, so I don't want anybody to get excited. All of them have directions right on the label. You snap the cap off, the top of the cap. It's grey on this particular thing. It's grey. You want to make sure you don't have your finger on the bottom because you're going to stick yourself, and you don't want to have it up here. You want to hold it like this, and you want to

go into the lateral, the side aspect of the thigh, and you inject it right in there. You can go right through the clothing.

You have to count to 10 very slowly—one-one thousand, two-one thousand—up to 10, to make sure that that medication goes in. You take it out very carefully, because there's going to be a needle sticking out and you don't want to stick yourself.

Then our procedure in our school district is anyone who gets epinephrine automatically goes to the emergency room in an ambulance, because you may need subsequent—

Senator DODD. The first thing you do is give the epinephrine, then you call 911.

Ms. KOSIOROWSKI. Yes.

Senator DODD. That's the order.

Ms. KOSIOROWSKI. Yes. Yes, you don't wait.

Senator DODD. What people may find startling, how much does an EpiPen cost?

Ms. KOSIOROWSKI. Well, we talked about that and one of the parents in our district told us that they buy two, because they tell you to have a backup. That's why I bought two. \$245. With insurance, they paid \$45. For families that don't have insurance, the cost is just unbelievable.

Senator DODD. And it's life-saving.

Senator ALEXANDER. How quickly do you need to administer that?

Senator DODD. Oh, quickly.

Ms. KOSIOROWSKI. As soon as you know that they're having an anaphylactic reaction. You don't wait.

Dr. SAMPSON. Yes, the sooner the better. The analogy we always use is a snowball rolling down a snowy hill. If you stop the snowball while it's this big at the top, it's very easy. Once it's moving and it's big, it may not be effective. Once the reaction is too far along, then the epinephrine may not even be effective. So the sooner the better.

Senator DODD. We should say, by the way, under the proposed bill we have, whatever State laws exist regarding the use of EpiPens are grandfathered in, so that there's no reason to go back and rewrite State legislation in this area. It automatically covers them in those situations as well.

I thank you for your demonstration on that.

I was going to ask you, doctor, if you could, what is your assessment of the state of surveillance efforts for food allergies at the Federal level, and do you believe there's a need for a national registry of food allergies?

Dr. SAMPSON. One of our biggest problems in trying to provide you with information is there is no good source of national data. I think one of the things that would help us understand the size of the problem and how to react to the problem better would be to have a clearinghouse, such as the CDC, that provides us with a register of actual numbers of reactions.

Most of the information we get are reports that people just find out about through reports in newspapers or members of FAAN, for example, who have heard about a reaction in their area. There is no organized approach currently standing to help us know how big the problem is.

Senator DODD. Well, that's something we might want to consider even with this legislation. It may be an advantage to have that.

Have we tried to do this? Does it take legislation? Couldn't they just do this on their own?

Dr. SAMPSON. I would probably defer to you on that, but I would think so.

Senator DODD. Let's inquire about that. Let me get a letter drafted and see if they can't just do this.

I wonder if you could discuss the—and I think you did already to some degree—the hygienic hypothesis in dealing with these non-infectious disorders?

Dr. SAMPSON. What lies behind the hygienic hypothesis is the fact that we have evolved as a species over the centuries with all these organisms that we confront all the time, and we have something called the primitive immune system, or the innate immune system, that requires interaction with these various bacteria and other organisms to set up the normal responsiveness of our immune system.

As Dr. Fauci also mentioned, without that stimulation you don't set the program for the immune system correctly. So that now, rather than seeing foods as harmless or other things, such as pollens or different substances in the environment that shouldn't bother any of us, the immune system in these individuals see this as a threat, and the IGE system or the allergic system that leads to most of the problem with food allergy was really evolving to protect us against parasitic infection and respond to parasitic infection, and that response has to be very severe. It's like using the cannon instead of the pistol in order to stop that.

Now, without exposure to many of these organisms and bacteria, which would allow us to program correctly, it now sees the food protein as though it were a parasite and causes this tremendous response of the body to try to protect us, and in fact it's misdirected and misfiring.

Senator DODD. Well, I guess more research will tell us and give us more confirmation of that approach.

You know, one area that, again someone raised it earlier because we talked about someone going into a restaurant and ordering a soup and ending up having a product in the soup that would cause someone to go into anaphylaxis—what advice to parents on going to restaurants? How do you try and deal with that situation? Do you have any advice on that?

Dr. SAMPSON. Yes. We actually encourage parents to be pretty aggressive, and sort of joke about sending them for aggressiveness training. You need to feel very confident when you tell one of the wait staff that you have a potentially life-threatening peanut allergy or milk allergy, and you need to be certain that there's no possibility that peanut or milk could be touching a particular food, and they go back into the kitchen. If they come back 10 seconds later and say, "no, it's fine," they clearly have not talked to the chef.

We even tell parents, if you're at all concerned—you go back and you talk to the staff back in the kitchens and the chefs and make sure that they really understand the potential for the problem, and

then if you're not comfortable you should just leave, that you shouldn't even attempt to eat anything if you're not comfortable.

Senator DODD. That's good advice, very good advice.

Donna, I wonder if—one of the things I was impressed with the school in West Haven, the Washington School—and I mentioned this in front of Dr. Sampson yesterday and others who were in the room—I liked the way you set that table aside, obviously, and you had the specifics on the milk allergy because even the physical contact could cause a reaction.

I also loved the fact that you have seats at that table for children who are getting their lunches prepared at school, where they are very careful about what's in those lunches, so that it's not a table exclusively for children with food allergies, because I think one of the real problems here is making someone feel as though they are so different, that those kind of pressures, particularly when they get older, will result in that young person saying: "I don't want to be different; I'm just not going to do this," and I'm going to then subject myself to many kinds of risks.

The fact that it was inclusive and allowed for their buddies and their pals to be sitting at that same table with them made a big difference, it seems to me.

Have you had instances—I'd like to hear about: No. 1, any kind of bullying that goes on; and No. 2, parents of nonallergic children, how they react to some of these things; and schools? Is there annoyance. Has there been anything at all you want to share with us on this committee about the problems you're seeing as a result of your efforts that you've made in West Haven, for instance?

Ms. KOSIOROWSKI. I think one of the keys is because Chris and Sue—those are two nurses in our district—are experts in food allergies and they've done a lot of training throughout the State and throughout the district. If the principal were here, he would tell you, this is what he says: "We don't isolate the kids, we don't let the allergies define who they are. We try to integrate them." We do have kids with peanut allergies and kids with milk allergies at the same table, but the kids with the milk allergies sit at the end. It's an opportunity to teach the other kinds about tolerance, about respect for other kids, about understanding that everybody's different.

We've had a few minor situations where, you know, if somebody knows somebody's got a milk allergy they'll take a piece of cheese and wave it in front of their face. The principal at that school is a real advocate for tolerance for all kids and he really takes that on.

When the kids understand what can happen, they have been extremely—I think kids are great. I think that if they understand and you talk to them, they have been extremely wonderful about doing this. It's really nice for kids because they don't want to be isolated from their friends; it's really nice for them to have the opportunity to sit together.

Senator DODD. That's great. That's wonderful.

I thank all of you. This has been very, very helpful. We have 11 co-sponsors of the bill already and I'll be talking to as many of my colleagues here in the Senate about this, and of course you

shouldn't feel reluctant about contacting any member of the Senate that you'd like them to join us in this effort.

The House has passed a bill. It does not include the grant money, which we think is very important, an important element. We're going to keep insisting upon that, so there's going to be resources. Schools are feeling a lot of pinching going on financially, for all the obvious reasons we're aware of. Providing at least the availability of some grant money that would allow them to put the guidelines into effect can be helpful. The money goes back to the school districts, by the way, not the States.

We'll leave the record open. I'm sure there are going to be additional questions for you in the coming days. This has been tremendously helpful.

Again, Ms. Walters, we thank you very, very much for being here. It means a great deal to have you here.

To you, Colene, we thank you very much for sharing your story with us.

Donna, I'm proud to represent you. You did a great job here as a Connecticut witness.

Dr. Sampson, we all admire immensely what you're doing. It's very exciting to hear you talk about some of these things. We want to keep you engaged and keep you informed. Any additional ideas and thoughts you have for us up here, we welcome them.

Kyle, we thank you, young man from Madison, CT, who's here, sat very patiently through all of this. I began to think maybe you thought being in school was maybe not a bad alternative to this. If you got to avoid school for a day, which was the better choice, sitting in a committee talking a lot of these \$20 words and the like. I'm very glad you came by.

Kyle, your allergies are to peanuts and tree nuts, right? Kyle, is that right?

Mr. ERICSON. Yes.

Senator DODD. Well, thank you very much for being here. It's nice to have you. Did you want to stand up so we can just see you here? You're a good young man, very good. Thank you very much. Thank your mom for bringing you down, and dad.

The committee will stand adjourned. We'll keep working on this. Good information, a good education session. Donna, you did a great job demonstrating the EpiPen, too.

The committee will stand adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF MARY R. ERICSON, MOTHER OF KYLE ERICSON

KYLE'S STORY

- Diagnosed with *life-threatening allergy to peanuts and tree nuts at 14 months old.*
- Has had reactions from *contact with trace amounts of peanut*—Examples: Sitting in a shopping cart at a grocery store where a previous child had eaten something with nuts; petting a dog who had just eaten a dog biscuit with peanut butter in it.
- Has been in daycare, camps and afterschool programs most of his life as both parents (John and I) work full-time.
- Was unable to safely attend the public school in Madison (New Haven County—CT) when entering first grade because the afterschool staff “were not permitted” to administer an EpiPen. The stated reason was that their “insurance carrier wouldn’t cover the liability.” We received a letter from the town informing us of this. That same letter stated that Kyle would, however, be allowed to “self-administer.”

Note:

1. The school doesn’t allow children to carry or administer any medication until they are in 6th grade and have parent and doctor permission.

2. At *6 years old*, Kyle couldn’t *open* a bottle of Benadryl and was not capable of using an EpiPen under healthy circumstances, let alone while experiencing an anaphylactic reaction!

3. We tried to fight this with extensive documentation, references to the ADA, doctors’ notes, and finally a private attorney. On August 6, 2004 we sent the Town of Madison a notice of intent to file formal complaint with the U.S. Office of Civil Rights specific to *Section 504 and ADA violation* per the town’s policy on self-administration of medications to treat life-threatening allergic reactions in the Madison Before/After School Program. *All of this was to no avail.* We enrolled Kyle in our local Catholic school—which does accommodate his needs both during the school day and in the aftercare program—where he and his brother now both attend.

• *Lacking federally endorsed guidelines for the management of food allergies, we have had to educate all of Kyle’s caretakers, teachers, and school staff* (including the nurses) about the nature of food allergies, the precautions that must be taken, and what to do in the event he accidentally comes in contact with or ingests nuts. Note that *the guidance we have provided school staff and caretakers is often different from guidance provided by other parents.*

• Kyle is now 10 years old; his 8-year-old brother Nicholas has no allergies. Neither parent has any food allergies.

• Kyle is the oldest of my parent’s nine grandchildren; two of the nine (including Kyle) have peanut and tree nut allergies—that’s more than *22 percent*. Another two of the nine are still babies, so we don’t know for sure about them yet.

While the Catholic school our children attend does an excellent job managing food allergies, *there are still challenges today for children in both public and private schools:*

• While legislation has been proposed in CT to have school bus drivers carry and be trained to administer EpiPens, currently, if a child has a reaction on a bus the driver is supposed to pull over, call 911 and wait.

• There are no consistent guidelines for managing food allergies in schools. So the management plan for one family from one doctor may be very different from those provided by other families and doctors. This creates uncertainty, concern and even hesitation among school staff and caretakers.

• The level of federally supported awareness programs and research is insufficient given the dramatically increasing statistics on children with food allergies.

While efforts within legislative scope are addressing the issues in schools, *food allergies affect families every day* in ways most people don’t think about. *Kids like Kyle help to make the severity of food allergies real to others who are still uninformed about just how serious this issue is.* He’s a great, smart, funny and active American kid. **But, he . . .**

- has to have an EpiPen and Benadryl with him everywhere he goes;
- wears a MedicAlert bracelet all the time;
- can’t sit with most of his friends at lunch at school; he sits at a nut-free table can’t drink out of water fountains (in case someone who ate nuts drank from the fountain and left traces);

- is sometimes afraid to go over friends houses because there could be hidden traces of nuts around (like the dog biscuit incident);
- can't go to Red Sox baseball games (or others, but he LOVES the Red Sox) because there are no food-free sections where he can safely sit without worrying about coming in contact with peanuts;
- has to have someone wipe down a seat in movie theaters to avoid contacting traces of nuts from previous people;
- is occasionally teased and bullied because of his allergy, the same way a child with a more visible physical disability might be teased;
- gets embarrassed on airplanes when they announce that there is a child allergic to peanuts on board;
- **has no memory of even one day when he wasn't aware that he could die from a peanut.**

Please accept my sincere thanks for your attention to food allergies, and my family's gratitude to Senator Dodd for his strong, personal commitment to this cause.

PREPARED STATEMENT OF JO FROST

For as long as I can remember as a little girl, I have lived with the burden of food allergies. Exposure to nuts and shellfish could send me to the hospital, gasping for air. The fear is real; it always has been and will continue to be a daily reality. When you suffer from extreme food allergies like I do, it is hard to trust restaurants, waiters, school cafeterias and even food packaging labels. This fear and lack of trust will remain with me like the memories of fighting for my life as each attack became worse. As a public figure and advocate for children, I feel it is my duty to help give a voice to those suffering with similar food allergy issues, so they don't have to grow up with that same fear instilled in them. Senator Dodd's Food Allergy and Anaphylaxis Management Act will allow children with these allergies to have a safe place where they don't have to worry if their lunch mate has brought a peanut butter sandwich in or if the school lunch they're eating has been cooked in peanut oil. Children should be free and open to learning and experiencing new things, school is a place to cultivate their learning and a safe haven from the world. A child should not have to worry about how close their inhaler or EpiPen is to their lunch tray or even if they might die while trying to retrieve it. Imagine being the parent (or perhaps you already are) of one of these children. You live in that same constant fear, the inability to control the situation or to protect your child. You drop them off at school, hoping, praying other parents won't forget and that fish/dairy won't be the only option on the school menu. Having to teach your children that it is not rude to not accept a sweet gesture of sharing another's lunch but merely a precaution to stay safe from what could be fatal.

I, as well as over 15 million others, am the people living with this raw reality of facts you've heard in this act. The fatal results of anaphylactic shock, the rise of peanut allergies and the knowledge that only eight foods account for 90 percent of food allergies. Eight simple foods while 3 million children suffer from these allergies, 30,000 of them are brought to the emergency room as a result of exposure and 200 die—remember that exposure to anaphylaxis to death can occur within minutes. Think of the weight of these numbers: 15 million vs. eight foods. The value of life and well-being is immeasurable, but here we're being presented with numbers to solidify something that should be a natural human right. I urge you all to support the act put forth by Senator Dodd. Work with me to protect these children, their health and most importantly, their lives so that they can have a future.

WHY THE FOOD ALLERGY AWARENESS PLAN WORKS AT WASHINGTON ELEMENTARY SCHOOL SUBMITTED BY DONNA RHODS-FROST

I am the parent of two children with life-threatening allergies. They also have other, less severe, food allergies. In the 8 years my children attended this school they experienced *no food allergic reaction*. In the same time period outside of school they experienced five adverse food reactions. How is that possible in an environment that would seem prone to allergen exposure?

1. A well-trained, knowledgeable, and caring nurse.
2. An administrative staff that was trained by the nurse in food allergy awareness.
3. A pool of volunteer teachers willing to take responsibility for the life of a child.
4. Exposure controls put in place and constantly monitored (i.e., peanut-free tables, notices of children with food allergies, recurrent training).
5. Personnel in food service who care and are aware of the risks of food allergies.

6. Teaching children in an environment that encourages consideration and respect for each other. This included a food allergy presentation in each classroom.

7. Children learn how to keep themselves safe over the course of their schooling here. To sit where it is safe for them to eat. They know adults are aware of their allergies. They know their teacher carries an EpiPen and food allergic students are encouraged to take responsibility for themselves as they progress. This prepares them for the middle school and high school environment where there are currently no controls for food allergy.

What could be better?

1. Funding to train all the teachers in a school. You cannot rely on just a handful of volunteers.

2. Awareness training for all nursing and administrative staff in a school system.

3. Discounts and funding for schools to purchase EpiPens on an annual basis. Many schools go without them or they are expired.

4. Food allergy awareness training for food service personnel.

5. A mechanism within the school lunch food program to avoid peanut/nut additives at the national level.

[Whereupon, at 4:53 p.m., the hearing was adjourned.]

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